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## *Targeting Hormone Pathways to Health*

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**GTx**

ANNUAL REPORT 2007



*GTx, Inc. is a biopharmaceutical company dedicated to the discovery, development, and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions.*

*GTx is developing Acapodene® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial evaluating Acapodene 80 mg for the treatment of multiple serious side effects of androgen deprivation therapy for advanced prostate cancer, and second, a pivotal Phase III clinical trial evaluating Acapodene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN. GTx licensed from Orion Corporation the rights to toremifene citrate for all indications worldwide, except breast cancer outside the United States. GTx has licensed to Ipsen Limited exclusive rights in Europe to develop and commercialize Acapodene. GTx plans to commercialize Acapodene in the United States.*

*GTx has formed a strategic collaboration with Merck & Co., Inc. for the development and global commercialization of selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to treat a variety of indications associated with muscle wasting and bone loss, including frailty or sarcopenia, muscle wasting associated with chronic diseases, osteoporosis, and cancer cachexia. GTx also is developing its preclinical compounds, GTx-753, an oral LH inhibitor for advanced prostate cancer, and GTx-878, an estrogen receptor beta agonist for the treatment of benign prostatic hyperplasia and chronic prostatitis.*



3 North Dunlap Street  
Memphis, Tennessee 38163  
(901) 523-9700

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March 12, 2008

Dear Stockholder:

I would like to extend a personal invitation for you to join us at our Annual Meeting of Stockholders on Wednesday, April 30, 2008, at 4:00 p.m. Central Daylight Time at the Toyota Center, 175 Toyota Plaza, Memphis, Tennessee 38103.

At this year's meeting, in addition to the election of two directors, you will be asked to approve GTx's 2004 Equity Incentive Plan, as amended, in order to permit GTx to grant stock options under that plan that satisfy the requirements for full tax deductibility. You will also be asked to ratify the appointment of Ernst & Young LLP as GTx's independent registered public accounting firm for 2008.

I urge you to vote, as the Board of Directors has recommended, for each of the director nominees and for the approval of GTx's 2004 Equity Incentive Plan, as amended. I also ask that you ratify the appointment of Ernst & Young LLP as GTx's independent registered public accounting firm for 2008.

Attached you will find a notice of meeting and proxy statement that contains further information about these items as well as specific details of the meeting.

**Your vote is important.** Whether or not you expect to attend the meeting, I encourage you to vote. Please sign and return your proxy card, or use the telephone or Internet voting prior to the meeting. This will assure that your shares will be represented and voted at the meeting, even if you cannot attend.

Sincerely,

Mitchell S. Steiner  
*Chief Executive Officer and  
Vice-Chairman of the Board of Directors*



3 North Dunlap Street  
Memphis, Tennessee 38163  
(901) 523-9700

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## NOTICE OF ANNUAL MEETING OF STOCKHOLDERS

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You are invited to attend the 2008 GTx, Inc. Annual Meeting of Stockholders:

- WHEN** 4:00 p.m. (Central Daylight Time) on Wednesday, April 30, 2008.
- WHERE** The Toyota Center, 175 Toyota Plaza, Memphis, Tennessee 38103.
- ITEMS OF BUSINESS**
- To elect two Class I directors to serve until the 2011 Annual Meeting of Stockholders and until their successors have been duly elected and qualified (Proposal 1);
  - To ratify the appointment of Ernst & Young LLP as GTx's independent registered public accounting firm for the fiscal year ending December 31, 2008 (Proposal 2);
  - To approve the GTx, Inc. 2004 Equity Incentive Plan, as amended (Proposal 3); and
  - To conduct such other business as may properly come before the meeting or any adjournment or postponement thereof.
- RECORD DATE** You are entitled to vote if you are a stockholder of record at the close of business on March 7, 2008.
- VOTING BY PROXY** The Board of Directors is soliciting your proxy to assure that a quorum is present and that your shares are represented and voted at the meeting. Please see the attached proxy statement and enclosed proxy card for information on submitting your proxy over the Internet, by telephone, or by mailing back the traditional proxy card (no extra postage is needed for the enclosed envelope if mailed in the U.S.). If you later decide to vote at the meeting, information on revoking your proxy prior to the meeting is also provided. You may receive more than one set of proxy materials and proxy cards. Please promptly complete, sign and return each proxy card you receive in order to ensure that all of your shares are represented and voted. Please note that if your shares are held of record by a broker, bank or other nominee and you wish to vote at the meeting, you must obtain a proxy issued in your name from that record holder.
- ATTENDANCE AT MEETING** If you plan to attend, please be sure to mark the box provided on the proxy card or indicate your attendance when prompted during your Internet or telephone submission.
- RECOMMENDATIONS** The Board of Directors recommends that you vote "FOR" each nominee for director and "FOR" each of Proposals 2 and 3.

**Your vote is important.** Whether or not you expect to attend the meeting, please submit your proxy promptly in order to assure that a quorum is present. Thank you for your attention to this important matter.

By Order of the Board of Directors,

Henry P. Doggrell  
*Vice President, General Counsel and Secretary*

Memphis, Tennessee  
March 12, 2008

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**GTx, Inc.**  
3 North Dunlap Street  
Memphis, Tennessee 38163  
(901) 523-9700

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**PROXY STATEMENT FOR THE  
2008 ANNUAL MEETING OF STOCKHOLDERS**

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The enclosed proxy is solicited by the Board of Directors of GTx, Inc. for use at the 2008 Annual Meeting of Stockholders. **Your vote is very important.** For this reason, the Board of Directors is requesting that you allow your shares to be represented at the 2008 Annual Meeting of Stockholders by the proxies named on the enclosed proxy card. In connection with the solicitation of proxies by the Board of Directors, we are mailing this proxy statement, the enclosed proxy card, and our 2007 Annual Report to all stockholders entitled to vote at the Annual Meeting beginning on or about March 21, 2008.

In this proxy statement, terms such as "we," "us" and "our" refer to GTx, Inc., which may also be referred to from time to time as "GTx."

**INFORMATION ABOUT THE MEETING**

**When is the Annual Meeting?**

The Annual Meeting will be held at 4:00 p.m., Central Daylight Time, on Wednesday, April 30, 2008.

**Where will the Annual Meeting be held?**

The Annual Meeting will be held at the Toyota Center, 175 Toyota Plaza, Memphis, Tennessee 38103.

**What items will be voted on at the Annual Meeting?**

There are three matters scheduled for a vote:

1. To elect two Class I directors to serve until the 2011 Annual Meeting of Stockholders and until their successors have been duly elected and qualified;
2. To ratify the appointment of Ernst & Young LLP as GTx's independent registered public accounting firm for the fiscal year ending December 31, 2008; and
3. To approve the GTx, Inc. 2004 Equity Incentive Plan, as amended.

As of the date of this proxy statement, we are not aware of any other matters that will be presented for consideration at the Annual Meeting.

**What are the Board of Directors' recommendations?**

Our Board of Directors recommends that you vote:

- "FOR" the election of each of the two nominees named herein to serve on the Board of Directors;
- "FOR" the ratification of the appointment of Ernst & Young LLP as GTx's independent registered public accounting firm for the fiscal year ending December 31, 2008; and
- "FOR" the approval of the GTx, Inc. 2004 Equity Incentive Plan, as amended.

## **Will GTx's directors be in attendance at the Annual Meeting?**

GTx encourages, but does not require, its directors to attend annual meetings of stockholders. However, GTx currently anticipates that all of its directors will attend the Annual Meeting. All but three of GTx's directors attended the 2007 Annual Meeting of Stockholders.

## **INFORMATION ABOUT VOTING**

### **Who is entitled to vote at the Annual Meeting?**

Only stockholders of record at the close of business on the record date, March 7, 2008, are entitled to receive notice of the Annual Meeting and to vote the shares for which they are stockholders of record on that date at the Annual Meeting, or any postponement or adjournment of the Annual Meeting. As of the close of business on March 7, 2008, GTx had 36,236,263 shares of common stock outstanding.

*Stockholders of Record: Shares Registered in Your Name.* If on March 7, 2008, your shares were registered directly in your name with GTx's transfer agent, Computershare Investor Services, then you are a stockholder of record. As a stockholder of record, you may vote in person at the Annual Meeting or vote by proxy. Whether or not you plan to attend the Annual Meeting, we urge you to fill out and return the enclosed proxy card, or vote by proxy over the telephone or on the Internet as instructed below, to ensure your vote is counted.

*Beneficial Owner: Shares Registered in the Name of a Broker or Bank.* If on March 7, 2008, your shares were held in an account at a brokerage firm, bank, dealer or other similar organization, then you are the beneficial owner of shares held in "street name" and these proxy materials are being forwarded to you by that organization. The organization holding your account is considered the stockholder of record for purposes of voting at the Annual Meeting. As a beneficial owner, you have the right to direct your broker or other agent on how to vote the shares in your account. You are also invited to attend the Annual Meeting. However, since you are not the stockholder of record, you may not vote your shares in person at the Annual Meeting unless you request and obtain a valid proxy from your broker or other agent.

### **How do I vote?**

You may either vote "FOR" each nominee to the Board of Directors or you may withhold your vote for any nominee. For each of the other matters to be voted on, you may vote "FOR" or "AGAINST" or abstain from voting. The procedures for voting are fairly simple:

*Stockholder of Record: Shares Registered in Your Name.* If you are a stockholder of record, you may vote in person at the Annual Meeting, vote by proxy using the enclosed proxy card, vote by proxy over the telephone, or vote by proxy on the Internet. Whether or not you plan to attend the Annual Meeting, we urge you to vote by proxy to ensure your vote is counted. You may still attend the Annual Meeting and vote in person if you have already voted by proxy.

- To vote in person, come to the Annual Meeting and we will give you a ballot when you arrive.
- To vote using the enclosed proxy card, simply complete, sign and date the enclosed proxy card and return it promptly in the postage paid envelope provided. If you return your signed proxy card to us before the Annual Meeting, we will vote your shares as you direct.
- To vote over the telephone, dial toll-free 1-800-652-8683 within the United States, Canada and Puerto Rico using a touch-tone phone and follow the recorded instructions. You will be asked to provide the company number and control number from the enclosed proxy card. Your vote must be received by 1:00 a.m., Central Daylight Time on April 29, 2008 to be counted.
- To vote on the Internet, go to [www.investorvote.com/gtxi](http://www.investorvote.com/gtxi) to complete an electronic proxy card. You will be asked to provide the company number and control number from the enclosed proxy card. Your vote must be received by 1:00 a.m., Central Daylight Time on April 29, 2008 to be counted.



*Beneficial Owner: Shares Registered in the Name of a Broker or Bank.* If you are a beneficial owner of shares registered in the name of your broker, bank or other agent, you should have received a proxy card and voting instructions with these proxy materials from that organization rather than from GTx. Simply complete and mail the proxy card to ensure that your vote is counted. Alternatively, you may vote by telephone or over the Internet as instructed by your broker or bank. To vote in person at the Annual Meeting, you must obtain a valid proxy from your broker, bank or other agent. Follow the instructions from your broker or bank included with these proxy materials, or contact your broker or bank to request a proxy form.

**We provide Internet proxy voting to allow you to vote your shares on-line, with procedures designed to ensure the authenticity and correctness of your proxy vote instructions. However, please be aware that you must bear any costs associated with your Internet access, such as usage charges from Internet access providers and telephone companies.**

#### **How many votes do I have?**

On each matter to be voted upon, you have one vote for each share of common stock for which you are the stockholder of record as of March 7, 2008.

#### **What if I return a proxy card but do not make specific choices?**

If you return a signed and dated proxy card without marking any voting selections, your shares will be voted "FOR" the election of both nominees for director, "FOR" the ratification of the appointment of Ernst & Young LLP as GTx's independent registered public accounting firm for the fiscal year ending December 31, 2008, and "FOR" the approval of the GTx, Inc. 2004 Equity Incentive Plan, as amended.

If any other matter is properly presented at the Annual Meeting, your proxy (one of the individuals named on your proxy card) will vote your shares as recommended by the Board of Directors or, if no recommendation is given, will vote your shares using his or her best judgment.

#### **Can I change my vote after submitting my proxy card?**

Yes. You can revoke your proxy at any time before the final vote at the Annual Meeting. If you are the record holder of your shares, you may revoke your proxy in any one of three ways:

- You may submit another properly completed proxy bearing a later date;
- You may send a written notice that you are revoking your proxy to GTx, Inc. at 3 North Dunlap Street, Memphis, Tennessee 38163, Attention: Henry P. Doggrell, Corporate Secretary; or
- You may attend the Annual Meeting and notify the election officials at the Annual Meeting that you wish to revoke your proxy and vote in person. Simply attending the Annual Meeting will not, by itself, revoke your proxy.

If your shares are held by your broker or bank as a nominee or agent, you should follow the instructions provided by your broker or bank.

#### **How are votes counted?**

Votes will be counted by the inspector of election appointed for the Annual Meeting, who will separately count "FOR" and withheld votes, and, with respect to proposals other than the election of the Class I directors, "AGAINST," "ABSTAIN" and broker non-votes. A broker non-vote occurs when a nominee, such as a broker or bank, holding shares for a beneficial owner does not vote on a particular proposal because the nominee does not have discretionary voting power with respect to that proposal and has not received instructions with respect to that proposal from the beneficial owner. In the event that a broker, bank, custodian, nominee or other record holder of our common stock indicates on a proxy that it does not have discretionary authority to vote certain shares on a particular proposal, then those shares will be treated as broker

non-votes with respect to that proposal. Accordingly, if you own shares through a nominee, such as a broker or bank, please be sure to instruct your nominee how to vote to ensure that your vote is counted on each of the proposals.

Abstentions and broker non-votes will be treated as shares present for the purpose of determining the presence of a quorum for the transaction of business at the Annual Meeting. Abstentions will be counted towards the tabulation of shares present in person or represented by proxy and will have the same effect as "AGAINST" votes on Proposals 2 and 3. Broker non-votes are not counted as votes "FOR" or "AGAINST" either Proposal 2 or Proposal 3.

#### **How many votes are needed to approve each proposal?**

- For the election of the Class I directors, the two nominees receiving the most "FOR" votes (among votes properly cast in person or by proxy) will be elected.
- To be approved, Proposal No. 2, the ratification of the appointment of Ernst & Young LLP as GTx's independent registered public accounting firm for the fiscal year ending December 31, 2008, must receive a "FOR" vote from at least a majority of the shares represented and voting either in person or by proxy at the Annual Meeting on Proposal No. 2.
- To be approved, Proposal No. 3, the approval of the GTx, Inc. 2004 Equity Incentive Plan, as amended, must receive a "FOR" vote from at least a majority of the shares represented and voting either in person or by proxy at the Annual Meeting on Proposal No. 3.

#### **How many shares must be present to constitute a quorum for the Annual Meeting?**

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if at least a majority of the outstanding shares entitled to vote are represented by stockholders present at the Annual Meeting or by proxy. On March 7, 2008, the record date, there were 36,236,263 shares outstanding and entitled to vote. Thus, at least 18,118,132 shares must be represented by stockholders present at the Annual Meeting or by proxy to have a quorum.

Your shares will be counted towards the quorum only if you submit a valid proxy (or one is submitted on your behalf by your broker, bank or other nominee) or if you vote in person at the Annual Meeting. Abstentions and broker non-votes will be treated as shares present for the purpose of determining the presence of a quorum. If there is no quorum, either the Chairman of the meeting or a majority of the votes present in person or represented by proxy at the Annual Meeting may adjourn the Annual Meeting to another date.

#### **How can I find out the results of the voting at the Annual Meeting?**

Preliminary voting results will be announced at the Annual Meeting. Final results will be published in GTx's quarterly report on Form 10-Q for the second quarter of 2008.

### **ADDITIONAL INFORMATION**

#### **How and when may I submit a stockholder proposal for GTx's 2009 Annual Meeting?**

Our annual meeting of stockholders generally is held in April or May of each year. We will consider for inclusion in our proxy materials for the 2009 Annual Meeting of Stockholders, stockholder proposals that are received at our executive offices no later than November 21, 2008 and that comply with all applicable requirements of Rule 14a-8 promulgated under the Securities Exchange Act of 1934, as amended. Proposals must be sent to our Corporate Secretary at GTx, Inc., 3 North Dunlap Street, Memphis, Tennessee 38163.

Pursuant to GTx's bylaws, stockholders wishing to submit proposals or director nominations that are not to be included in our proxy materials must have given timely notice thereof in writing to our Corporate Secretary. To be timely for the 2009 Annual Meeting of Stockholders, you must notify our Corporate Secretary, in writing, not later than the close of business on November 21, 2008, nor earlier than the close of business on October 22, 2008. We also advise you to review GTx's bylaws, which contain additional requirements about advance notice of stockholder proposals and director nominations, including the different notice submission date requirements in the event that we do not hold our 2009 Annual

Meeting of Stockholders between March 31, 2009 and May 30, 2009. The Chairman of the 2009 Annual Meeting of Stockholders may determine, if the facts warrant, that a matter has not been properly brought before the meeting and, therefore, may not be considered at the meeting. In addition, the proxy solicited by the Board of Directors for the 2009 Annual Meeting of Stockholders will confer discretionary voting authority with respect to (i) any proposal presented by a stockholder at that meeting for which GTx has not been provided with timely notice and (ii) any proposal made in accordance with the GTx's bylaws, if the 2009 proxy statement briefly describes the matter and how management's proxy holders intend to vote on it, if the stockholder does not comply with the requirements of Rule 14a-4(c)(2) promulgated under the Securities Exchange Act of 1934.

If a stockholder is recommending a candidate to serve on the Board of Directors, the recommendation must include the information specified in GTx's bylaws, including the following:

- the stockholder's name and address and the beneficial owner, if any, on whose behalf the nomination is proposed;
- the class and number of shares of GTx which are owned beneficially and of record by such stockholder and such beneficial owner;
- a description of all arrangements or understandings between the stockholder and the proposed nominee and any other person or persons regarding the nomination;
- the nominee's written consent to being named in GTx's proxy statement as a nominee and to serving as a director if elected; and
- all information regarding the nominee that would be required to be included in GTx's proxy statement by the rules of the SEC, including the nominee's age, business experience for the past five years and any other directorships held by the nominee.

#### **How can I obtain GTx's Annual Report on Form 10-K?**

A stockholders' letter and a copy of our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, which together constitutes our 2007 Annual Report to Stockholders, is being mailed along with this proxy statement. Our 2007 Annual Report is not incorporated into this proxy statement and shall not be considered proxy solicitation material.

We will also mail to you without charge, upon written request, a copy of our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, as well as a copy of any exhibit specifically requested. Requests should be sent to: Corporate Secretary, GTx, Inc., 3 North Dunlap Street, Memphis, Tennessee 38163. A copy of our Annual Report on Form 10-K has also been filed with the SEC and may be accessed from the SEC's homepage ([www.sec.gov](http://www.sec.gov)).

#### **Who is paying for this proxy solicitation?**

We will pay for the entire cost of soliciting proxies. We are paying The Altman Group, Inc. their customary fee of \$1,025 plus out-of-pocket expenses to solicit proxies. In addition to these mailed proxy materials, our directors and employees may also solicit proxies in person, by telephone or by other means of communication. Directors and employees will not be paid any additional compensation for soliciting proxies. We may also reimburse brokerage firms, banks and other agents for the cost of forwarding proxy materials to beneficial owners.

#### **How many copies should I receive if I share an address with another stockholder?**

The SEC has adopted rules that permit companies and intermediaries, such as brokers, to satisfy the delivery requirements for proxy statements and annual reports with respect to two or more stockholders sharing the same address by delivering a single proxy statement addressed to those stockholders. This process, which is commonly referred to as "householding," potentially provides extra convenience for stockholders and cost savings for companies.

This year, a number of brokers with account holders who are GTx stockholders will be householding our proxy materials by delivering a single proxy statement and annual report to multiple stockholders sharing an address unless contrary instructions have been received from the affected stockholders. Once you have received notice from your broker that it will be householding materials to your address, householding will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in householding and would prefer to receive a separate proxy statement and annual report in the future you may notify your broker or GTx. You can notify us by sending a written request to GTx, Inc., c/o Henry P. Doggrell, Corporate Secretary, 3 North Dunlap Street, Memphis, Tennessee 38163, or by calling 901-523-9700. Stockholders who currently receive multiple copies of the proxy statement and annual report at their address and would like to request "householding" of their communications should contact their broker. In addition, GTx will promptly deliver, upon written or oral request to the address or telephone number above, a separate copy of the annual report and proxy statement to a stockholder at a shared address to which a single copy of the documents was delivered.

**Who should I contact if I have any questions?**

If you have any questions about the Annual Meeting, these proxy materials or your ownership of our common stock, please contact McDavid Stilwell, Director, Corporate Communications and Financial Analysis, 3 North Dunlap Street, Memphis, Tennessee 38163, Telephone 901-523-9700 ext. 214 or by Fax: 901-844-8075.

## **PROPOSAL NO. 1 ELECTION OF DIRECTORS**

GTx's Board of Directors is divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors, and each class has a three-year term. Only persons elected by a majority of the remaining directors may fill vacancies on the Board. A director elected by the Board to fill a vacancy in a class shall serve for the remainder of the full term of that class and until the director's successor is elected and qualified. This includes vacancies created by an increase in the number of directors.

The Board of Directors presently has ten members, and as of the Annual Meeting, with the recently announced retirement of Mr. Clarkson from the Board, there will be nine members. There are currently three directors in Class I, the class whose term of office expires in 2008, two of whom are standing for election. Robert W. Karr, M.D. and Rosemary Mazanet, M.D., Ph.D., each of whom is a current director, was recommended for election to our Board of Directors by our Nominating and Corporate Governance Committee and was nominated for re-election by the Board of Directors. Dr. Karr was originally recommended to serve on our Board of Directors by Dr. Steiner, our Chief Executive Officer, and Mr. Hanover, our Chief Operating Officer, who were told by a pharmaceutical industry consultant that Dr. Karr was then retiring from Pfizer, Inc. and may be amenable to consider serving on GTx's Board of Directors. If elected at the Annual Meeting, Dr. Karr and Dr. Mazanet will serve until the 2011 Annual Meeting of Stockholders and until their successors are elected and qualified, or until their earlier death, resignation or removal. Mr. Clarkson, currently a Class I director, has advised the Board of Directors that he intends to retire from the Board and will not stand for re-election at the 2008 Annual Meeting. As a result, proxies may not be voted for more than two directors. The Nominating and Corporate Governance Committee will determine if one or more persons should be added to the Board as a result of Mr. Clarkson's departure and if so, it will follow the established process in identifying and recommending appropriate Board candidates. See "Additional Information About the Board of Directors—Nominating and Corporate Governance Committee Matters" below.

Directors are elected by a plurality of the votes present in person or represented by proxy and entitled to vote at the Annual Meeting. Shares represented by executed proxies will be voted, if authority to do so is not withheld, for the election of each of Dr. Karr and Dr. Mazanet. In the event that any nominee should be unavailable for election as a result of an unexpected occurrence, such shares will be voted for the election of such substitute nominee as the Nominating and Corporate Governance Committee may propose. Dr. Karr and Dr. Mazanet have each agreed to serve if elected.

The following is a brief biography of each nominee standing for election to the Board of Directors at the Annual Meeting.

### **Class I Director Nominees for Election for a Three-Year Term Expiring at the 2011 Annual Meeting**

#### **Robert W. Karr, M.D.**

Dr. Karr, age 59, has served as a director since June 2005 and currently serves on the Nominating and Corporate Governance Committee. Dr. Karr served as President of Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) from December 2005 until December 2007. He currently serves on its Board of Directors and as a consultant. Since January 2008, Dr. Karr has also served as a consultant for Karr Pharma Consulting, LLC. From 2000 to 2004, Dr. Karr was a senior executive for Global Research & Development for Pfizer, Inc. (NYSE: PFE), where he served as Senior Vice President, Strategic Management from 2002 to 2004. Prior to its merger with Pfizer, Dr. Karr served as Vice President, Research & Development Strategy for Warner-Lambert Company. Dr. Karr received his B.S. (with honors) from Southwestern University in 1971 and his M.D. from the University of Texas Medical Branch in 1975. Dr. Karr completed his internship and residency in internal medicine at Washington University School of Medicine and served as a faculty member at both the University of Iowa College of Medicine and Washington University School of Medicine.

#### **Rosemary Mazanet, M.D., Ph.D.**

Dr. Mazanet, age 52, has served as a director since October 2001 and currently serves on the Nominating and Corporate Governance Committee. Since May 2007, Dr. Mazanet has served as a portfolio manager for Argenis Capital Advisors, LLC, a public equity fund. From 2004 to 2007, Dr. Mazanet served as the Chief Executive Officer of Breakthrough Therapeutics, LLC, a therapeutic development company. She also served as acting Chief Executive Officer of Access Pharmaceuticals (AMEX: AKC) from May 2005 until January 2007 and remains a director. From June 1998 to February 2004, Dr. Mazanet served as Chief Scientific Officer and a General Partner of Oracle Partners, L.P., a hedge fund. Prior to joining Oracle Partners, Dr. Mazanet served as Senior Director of Clinical Research at Amgen, Inc., a

pharmaceutical company. Dr. Mazanet is a member of the Board of Trustees of the University of Pennsylvania School of Medicine. She trained in internal medicine at the Brigham and Women's Hospital and in oncology at the Dana Farber Cancer Institute, both part of the Harvard Medical system, where she was a staff physician prior to joining Amgen. Dr. Mazanet holds a B.A. in Biology from the University of Virginia and an M.D. and a Ph.D. from the University of Pennsylvania.

*The Board of Directors recommends a vote in favor of each of the nominees for Class I Director.*

## **ADDITIONAL INFORMATION ABOUT THE BOARD OF DIRECTORS**

### **Continuing Directors**

In addition to the two Class I director nominees, GTx has seven other directors who will continue in office after the Annual Meeting with terms expiring in 2009 and 2010. The following directors compose the remainder of the Board with terms expiring as shown.

### **Class II Director Continuing in Office Until the 2009 Annual Meeting**

#### **J. Kenneth Glass**

Mr. Glass, age 61, has served as a director since March 2004 and currently serves on the Audit Committee and the Compensation Committee. Mr. Glass retired as Chairman of the Board, President and CEO of First Horizon National Corporation, or First Horizon, as of January 29, 2007. Mr. Glass was named President and Chief Executive Officer of First Horizon in July 2002, and he also became First Horizon's Chairman of the Board in January 2004. From July 2001 through July 2002, Mr. Glass was President and Chief Operating Officer of First Horizon. From 1993 to 2001, Mr. Glass was Business Unit President of First Tennessee Bank. Mr. Glass received his B.A. in Accounting from Harding University and graduated from Harvard Business School's Advanced Management Program.

#### **Marc S. Hanover**

Mr. Hanover, age 45, a co-founder of GTx, has served as our President and Chief Operating Officer and a director since our inception in September 1997. Prior to joining GTx, Mr. Hanover was a founder of Equity Partners International, Inc., a private equity firm in Memphis, Tennessee, and participated as a founder and investor in three healthcare companies. From 1985 to 1997, Mr. Hanover was a Senior Vice President and a member of the Executive Management Committee of National Bank of Commerce in Memphis, Tennessee. Mr. Hanover holds a B.S. in Biology from the University of Memphis and an MBA in Finance from the University of Memphis.

#### **John H. Pontius**

Mr. Pontius, age 52, has served as a director since April 1998 and currently serves as Chairman of the Nominating and Corporate Governance Committee. Mr. Pontius has been the President of Pittco Management, LLC, an investment and business management firm, since 1991. From 1986 to 1991, Mr. Pontius served as the Chief Financial Officer of the City of Memphis, Tennessee. Mr. Pontius holds a B.S. in Accounting from the University of Tennessee. Mr. Pontius served as a member of the Board of Trustees of the University of Tennessee from 2002 to 2004.

### **Class III Directors Continuing in Office Until the 2010 Annual Meeting**

#### **Michael G. Carter, M.D., Ch.B., F.R.C.P.**

Dr. Carter, age 70, was appointed as a director in May 2006 and currently serves on the Compensation Committee. Dr. Carter is a non-executive director of Micromet, Inc. (Nasdaq: MITI), Santarus, Inc. (Nasdaq: SNTS) and Fulcrum Pharma, PLC (AIM: FUL). Dr. Carter has served as the non-executive chairman of Metris Therapeutics, Ltd., a biotechnology firm specializing in women's healthcare since 1999. He is a member of the Advisory Board of Paul Capital Royalty Fund and was a venture partner with SV Life Sciences Advisers, LLP from 1998 to 2006. Dr. Carter served on the Pharmaceutical Board of Zeneca Pharmaceuticals, a predecessor company of AstraZeneca, and held various positions with Zeneca from 1984 to 1998, including International Medical Director and International Marketing Director. From 1985 to

1995, Dr. Carter served as a member of the U.K. Government's Medicines Commission. Dr. Carter is an Elected Fellow of the Royal Pharmaceutical Society, Faculty of Pharmaceutical Medicine, and of the Royal College of Physicians of Edinburgh. Dr. Carter holds a bachelor's degree in pharmacy from London University (U.K.) and a medical degree from Sheffield University Medical School (U.K.).

### **J. R. Hyde, III**

Mr. Hyde, age 65, has served as the Chairman of our Board of Directors since November 2000 and currently serves as Chairman of the Compensation Committee. Since 1989, Mr. Hyde has been the sole stockholder and President of Pittco Holdings, Inc., a private institutional investment company. Since 1996, when Mr. Hyde made a substantial contribution to support Dr. Steiner's research, Mr. Hyde has been instrumental in forming and financing GTx and is our largest stockholder. Mr. Hyde was the Chairman of the Board of Directors of AutoZone, Inc. (NYSE: AZO) from 1986 to 1997 and the Chief Executive Officer of AutoZone from 1986 to 1996. He was also Chairman and Chief Executive Officer of Malone & Hyde, Inc., AutoZone's former parent company, from 1972 until 1988. Mr. Hyde currently is a director of AutoZone, Inc. and FedEx Corporation (NYSE: FDX), and in March 2005, Mr. Hyde was appointed as the non-executive chairman of the Board of Directors of AutoZone, Inc.

### **Timothy R. G. Sear**

Mr. Sear, age 70, was appointed as a director in October 2004 and currently serves on the Audit Committee and the Compensation Committee. Mr. Sear serves as Chairman Emeritus of Alcon, Inc. (NYSE: ACL), having retired from the offices of President and Chief Executive Officer on September 30, 2004. Prior to serving as President and Chief Executive Officer of Alcon, Mr. Sear served as Executive Vice President for Alcon's U.S. Operations from 1996 through 1997 and also as Executive Vice President for Alcon's International Division from 1988 to 1996. Mr. Sear is a graduate of Manchester University in the U.K. and Copenhagen University, Denmark and received an MBA in International Business from Indiana University. He is also a graduate of Harvard Business School's Advanced Management Program. Mr. Sear is a director of Sigma-Aldrich, Inc. (Nasdaq: SIAL), and Mr. Sear currently serves as Chairman of the Board of Directors of Prometheus Laboratories Inc.

### **Mitchell S. Steiner, M.D., F.A.C.S.**

Dr. Steiner, age 47, a co-founder of GTx, has served as our Chief Executive Officer and Vice-Chairman of our Board of Directors since GTx's inception in September 1997. From 1995 to 2003, Dr. Steiner held numerous academic appointments, including Chairman and Professor of Urology, Director of Urologic Oncology and Research and the Chair of Excellence in Urologic Oncology at the University of Tennessee. Since 2003, Dr. Steiner has continued to serve on the faculty at the University of Tennessee. Dr. Steiner holds a B.A. in Molecular Biology from Vanderbilt University and an M.D. from the University of Tennessee, and performed his surgery and urologic training at The Johns Hopkins Hospital.

### **Director Independence**

As required under the Nasdaq listing standards, a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the Board of Directors. Consistent with the requirements of the SEC, the Nasdaq and general corporate "best practices" proposals, our Board of Directors reviews all relevant transactions or relationships between each director, and GTx, its senior management and its independent auditors. During this review, the Board considers whether there are any transactions or relationships between directors or any member of their immediate family (or any entity of which a director or an immediate family member is an executive officer, general partner or significant equity holder) and members of GTx's senior management or their affiliates. The Board consults with GTx's corporate counsel to ensure that the Board's determinations are consistent with all relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent Nasdaq listing standards, as in effect from time to time.

As a result of this review, the Board affirmatively determined that the following eight of our ten directors are independent members of the Board of Directors within the meaning of the applicable Nasdaq listing standards: Mr. Hyde (Chairman), Dr. Carter, Mr. Clarkson, Mr. Glass, Dr. Karr (Nominee), Dr. Mazanet (Nominee), Mr. Pontius, and Mr. Sear. As a result of Mr. Hyde's stock ownership in GTx and Mr. Pontius' affiliation with Mr. Hyde, neither Mr. Hyde nor Mr. Pontius are considered "independent" under applicable Nasdaq and SEC standards pertaining to membership of the Audit Committee (neither Mr. Hyde nor Mr. Pontius are members of the Audit Committee, however). Dr. Steiner, our Chief

Executive Officer, and Mr. Hanover, our President and Chief Operating Officer, are not “independent” within the meaning of the Nasdaq listing standards.

The Compensation Committee and the Nominating and Corporate Governance Committee of the Board are comprised entirely of directors who are independent within the meaning of the Nasdaq listing standards, and the members of the Audit Committee are independent under applicable Nasdaq listing standards and SEC rules. In addition, the Board of Directors has determined that each member of the Audit Committee qualifies as an “audit committee financial expert” within the meaning of the SEC rules.

### Board and Committee Meetings; Attendance

GTx encourages, but does not require its directors to attend annual meetings of stockholders. All but three of our directors attended the 2007 Annual Meeting of Stockholders. For 2007, the average aggregate Board and committee meeting attendance for all current directors was approximately 96%, with each director attending at least 75% of the aggregate of (a) all meetings of the Board and (b) any committees on which he or she served. In 2007, the Board of Directors held six meetings, and the number of meetings held by the Board committees is set forth in the table below. In addition, our non-management directors hold executive sessions after the conclusion of each regularly scheduled Board meeting. Mr. Hyde presides as Chairman over each executive session of the Board.

### Board Committees

The charters for the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee are available on GTx’s website ([www.gtxinc.com](http://www.gtxinc.com)) under “About GTx” at “Corporate Governance.” The current membership of and information about each of our Board committees are shown below.

Committee/Current Members	Committee Functions
<b>Audit Committee</b>  <i>Current Members</i> Mr. Clarkson* (Chairman) Mr. Glass Mr. Sear  <i>Number of Meetings held in 2007: Five</i>	<ul style="list-style-type: none"> <li>• Oversees financial and operational matters involving accounting, corporate finance, internal and independent auditing, internal control over financial reporting, compliance, and business ethics.</li> <li>• Oversees other financial audit and compliance functions as assigned by the Board.</li> <li>• Reviews areas of potential significant financial risk to GTx.</li> <li>• Has the sole authority to select, evaluate, replace and oversee GTx’s independent registered public accounting firm.</li> <li>• Has the sole authority to approve non-audit and audit services to be performed by the independent registered public accounting firm.</li> <li>• Monitors the independence and performance of the independent registered public accounting firm.</li> <li>• Provides an avenue of communications among the independent registered public accounting firm, management and the Board of Directors.</li> <li>• Determines whether “related party transactions” are permissible.</li> <li>• Has the specific responsibilities and authority necessary to comply with the Nasdaq listing standards applicable to audit committees.</li> </ul>
<b>Compensation Committee</b>  <i>Current Members:</i> Mr. Hyde (Chairman) Dr. Carter Mr. Glass Mr. Sear  <i>Number of Meetings held in 2007: Six</i>	<ul style="list-style-type: none"> <li>• Reviews the performance of GTx officers and establishes overall executive compensation policies and programs.</li> <li>• Reviews and approves compensation elements such as base salary, bonus awards, stock option grants and other forms of long-term incentives for GTx officers (no member of the committee may be a member of management or eligible for compensation other than as a director).</li> <li>• Reviews Board compensation and stock ownership matters.</li> <li>• Reviews and discusses with management the information contained in the Compensation Discussion and Analysis section of the proxy statement.</li> </ul>



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**Nominating and Corporate Governance Committee*****Current Members:***

Mr. Pontius (Chairman)

Dr. Karr

Dr. Mazanet

*Number of Meetings held in 2007:* Four

- Evaluates governance standards for GTx to ensure that appropriate governance policies and procedures have been established and are being followed.
- Develops criteria to determine the qualifications and appropriate tenure of directors.
- Reviews such qualifications and makes recommendations to the Board regarding the nomination of current directors for re-election to the Board as well as new nominees to fill vacancies on the Board.
- Considers stockholder recommendations for Board nominees, as described below.
- Recommends to the Board the chairmanship and membership of each Board committee.
- Considers applicable social and ethical issues and other matters of significance in areas related to corporate public affairs.
- Reviews succession plans for GTx officers.

\* Mr. Clarkson has served as Chairman of the Audit Committee since March 2004; however, Mr. Clarkson is not standing for re-election at the 2008 Annual Meeting. The Board of Directors, upon the recommendation of the Nominating and Corporate Governance Committee, has appointed Mr. Glass, a current member of the Audit Committee, as Chairman of the Audit Committee, effective upon the expiration of Mr. Clarkson's term at the Annual Meeting. We currently expect that Dr. Mazanet, an independent director, will become a member of the Audit Committee in connection with Mr. Clarkson's departure from the Board.

**Nominating and Corporate Governance Committee Matters**

The Nominating and Corporate Governance Committee expects, as minimum qualifications, that nominees to the Board (including incumbent directors) will enhance the Board's management, finance and/or scientific expertise, will not have a conflict of interest and will have a high ethical standard and, with respect to new members of the Board, a willingness to serve at least an initial three year term for the committee, to recommend them to the Board of Directors. A director nominee's knowledge and/or experience in areas such as, but not limited to, the medical, pharmaceutical, biotechnology, biopharmaceutical or life sciences industry, equity and debt capital markets and financial accounting are likely to be considered both in relation to the individual's qualification to serve on our Board of Directors and the needs of the Board as a whole. Other characteristics, including but not limited to, the director nominee's material relationships with GTx, time availability, service on other boards of directors and their committees, or any other characteristics which may prove relevant at any given time as determined by the Nominating and Corporate Governance Committee are reviewed for purposes of determining a director nominee's qualification.

Candidates for director nominees are evaluated by the Nominating and Corporate Governance Committee in the context of the current composition of the Board, the operating requirements of GTx and the long-term interests of GTx's stockholders. In the case of new director candidates, the Nominating and Corporate Governance Committee also determines whether the nominee must be independent for Nasdaq purposes, which determination is based upon applicable Nasdaq listing standards, applicable SEC rules and regulations and the advice of counsel, if necessary. The Nominating and Corporate Governance Committee then uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm. The Nominating and Corporate Governance Committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board. In the case of incumbent directors whose terms of office are set to expire, the Nominating and Corporate Governance Committee reviews such directors' overall service to GTx during their term, including the number of meetings attended, level of participation, quality of performance, and any other relationships and transactions that might impair such directors' independence. The Nominating and Corporate Governance Committee meets to discuss and consider such candidates' qualifications and then selects a nominee for recommendation to the Board by majority vote. The Nominating and Corporate Governance Committee does not intend to alter the manner in which it evaluates candidates, including the minimum criteria set forth above, based on whether the candidate was recommended by a stockholder or not. To date, the Nominating and Corporate Governance Committee has not paid a fee to any third party to assist in the process of identifying or evaluating director candidates.

The Nominating and Corporate Governance Committee has evaluated and recommended each of the directors currently standing for re-election at the Annual Meeting and will determine if one or more persons should be added to the Board as a result of Mr. Clarkson's departure and if so, it will follow the established process in identifying and recommending appropriate Board candidates.

The Board of Directors does not impose term limits or a mandatory retirement age for directors, except GTx's chief executive officer and chief operating officer are required to leave the Board if he or she ceases to serve as GTx's chief executive officer or chief operating officer, as the case may be. While it is believed that a director's knowledge and/or experience can continue to provide benefit to the Board of Directors following a director's retirement from his or her primary work affiliation, it is recognized that a director's knowledge of and involvement in ever changing business environments can weaken, and therefore his or her ability to continue to be an active contributor to the Board of Directors shall be reviewed. Upon a director's change in employment status, he or she is required to notify the Chairman of the Board of Directors and the Chair of the Nominating and Corporate Governance Committee of such change and to offer his or her resignation for review.

### **Compensation Committee Matters**

*Scope of Authority.* The Compensation Committee acts on behalf of the Board of Directors to establish the compensation of executive officers of GTx and provides oversight of GTx's compensation philosophy. The Compensation Committee also acts as the oversight committee with respect to GTx's benefit plans, stock plans and bonus plans covering executive officers and other senior management. In overseeing those plans, the Compensation Committee has the sole authority for day-to-day administration and interpretation of the plans. Our Compensation Committee retains the authority for establishing all matters with respect to the compensation of our executive officers, although our Compensation Committee may recommend to the full Board of Directors that it take action with respect to such compensation matters. The Compensation Committee has the authority to engage outside advisors to assist the Committee in the performance of its duties; however, the Compensation Committee may not delegate its authority to others.

Mr. Hyde, as Chairman of the Compensation Committee, is responsible for setting the agenda for meetings. Our Compensation Committee annually evaluates the performance, and determines the compensation, of the Chief Executive Officer and the other executive officers of GTx. More information regarding the Compensation Committee's process and procedures for determining and evaluating our executive officers' compensation packages can be found under the caption "Compensation Discussion and Analysis" below.

*Compensation Consultants.* Under its charter, the Compensation Committee has the power and authority to hire outside advisors or consultants to assist it in fulfilling its responsibilities upon terms and conditions established by the Compensation Committee. GTx is financially responsible for the fees of any advisor or consultant engaged by the Compensation Committee. In 2006, the Compensation Committee retained one compensation consultant, Mercer Human Resource Consulting, or Mercer, to assist with the Committee's analysis and determination of the 2007 compensation of our executive officers. The Committee was informed that Mercer also was retained by GTx to assist it in evaluating salary ranges for various employee levels within GTx, but since the Compensation Committee retained the sole power and authority to establish the nature and scope of Mercer's engagement, set the fee to be paid to Mercer and to terminate Mercer's engagement, the Compensation Committee determined that its relationship with Mercer was sufficiently independent of the services Mercer was rendering for GTx. The Compensation Committee directed Mercer to review GTx's executive compensation program and to recommend changes as deemed appropriate to ensure that GTx's compensation program provides reasonable and competitive pay opportunities that are aligned with key business objectives and best practices. In 2007, the Compensation Committee reviewed executive compensation data developed by Equilar, Inc., or Equilar, a web-based independent executive compensation firm, which compensation data included base salary, bonus compensation and equity and/or stock option awards received by the chief executive officer, president and other executive officers of a peer group of companies selected by the Compensation Committee.

*Roles of Executives in Establishing Compensation.* Our Chief Executive Officer, Dr. Steiner, provides to the Compensation Committee an annual performance review of each of our other executive officers which is considered by the Compensation Committee in its determination of compensation for such officers. Dr. Steiner and our Chief Operating Officer, Mr. Hanover, also recommend to the Compensation Committee the number of stock options to be granted to new hires and existing employees, subject to guidance provided to them by the Chairman of the Compensation Committee and consistent with the data supplied by the Committee's compensation consultants regarding GTx's peer group. It is within the prerogative of the Compensation Committee to approve, modify or disapprove any recommendations for grants of options to GTx employees. Dr. Steiner and Mr. Hanover also provide recommendations to the Compensation Committee with

respect to the specific performance goals to be achieved to receive executive bonus compensation under GTx's Executive Bonus Compensation Plan. Additional information on the role of our executive officers in establishing compensation can be found under the caption "Compensation Discussion and Analysis" below.

**Director Compensation.** The Board of Directors sets non-management directors' compensation at the recommendations of the Nominating and Corporate Governance Committee and the Compensation Committee. Periodically, at the request of the Nominating and Corporate Governance Committee, GTx's management provides the committee with information relating to director compensation paid by comparable companies, based on the peer group of biopharmaceutical companies established for the purpose of competitive compensation comparisons through the Mercer engagement in 2006. The Nominating and Corporate Governance Committee uses this information in making its recommendations to the Compensation Committee about whether and to what extent director compensation should be modified. The Compensation Committee considers the information supplied by the Nominating and Corporate Governance Committee and that committee's recommendations and determines whether it will recommend to the Board of Directors that the Board of Directors consider approving any modifications or additions to the compensation paid to directors by GTx. The Compensation Committee and Board of Directors believe that: director compensation should fairly compensate directors for work required in a company of GTx's size and scope; the compensation should align directors' interests with the long-term interest of stockholders; and the structure of the compensation should be simple, transparent and easy for stockholders to understand. We pay our non-employee directors retainers in quarterly increments based on an annualized rate of \$20,000 a year, or \$30,000 a year for our Audit Committee Chair. Based on the data and market information from the companies in our peer group, in 2007, the Board of Directors approved the Compensation Committee's recommendation to pay each non-employee director a fee of \$1,500 for every Board and committee meeting attended (and \$750 for any telephonic meeting attended) in addition to the director's annual retainer.

**Compensation Committee Charter.** Our Compensation Committee reviews its charter on an annual basis and, if necessary, recommends changes to the Board of Directors for its approval. A copy of the Compensation Committee's charter can be found on our corporate website at [www.gtxinc.com](http://www.gtxinc.com) under "About GTx" at "Corporate Governance."

#### **Stockholder Nomination Policy**

It is the Nominating and Corporate Governance Committee's policy to review and consider all candidates for nomination and election as directors who may be suggested by any director or executive officer of GTx. The Nominating and Corporate Governance Committee will also consider any director candidate recommended by any stockholder if the recommendation is made in accordance with GTx's charter, bylaws and applicable law. To be considered, a recommendation for director nomination should be submitted in writing to: GTx, Inc., Nominating and Corporate Governance Committee, Attention: Corporate Secretary, 3 North Dunlap Street, Memphis, Tennessee 38163. If you would like to recommend a director candidate, you must follow the procedures outlined above under the caption "Additional Information -- How and when may I submit a stockholder proposal for GTx's 2009 Annual Meeting?"

#### **Code of Business Conduct and Ethics and Guidelines on Governance Issues**

Our Board of Directors has adopted a Code of Business Conduct and Ethics applicable to all officers, directors and employees as well as Guidelines on Governance Issues. These documents were recently reviewed by our Nominating and Corporate Governance Committee and their recommended changes, clarifications and additions were accepted and approved by the Board. These documents are available on GTx's website ([www.gtxinc.com](http://www.gtxinc.com)) under "About GTx" at "Corporate Governance." GTx will provide a copy of these documents to any person, without charge, upon request, by writing to: GTx, Inc., Director, Corporate Communications and Financial Analysis, 3 North Dunlap Street, Memphis, Tennessee 38163. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of the Code of Business Conduct and Ethics by posting such information on our website at the address and the locations specified above.

#### **Communications with the Board**

Stockholders and other interested parties may communicate in writing with our Board of Directors, any of its committees, or with any of its non-management directors by sending written communications addressed to: GTx, Inc., Attention: Corporate Secretary, 3 North Dunlap Street, Memphis, Tennessee 38163. Our Corporate Secretary will review each communication and will forward such communication to the Board or to any individual director to whom the

communication is addressed unless the communication is unduly hostile, threatening or similarly inappropriate, in which case, the Secretary will discard the communication.

### **Policies on Reporting Certain Concerns Regarding Accounting and Other Matters**

We have adopted policies on the reporting of concerns to our Compliance Officer and Audit Committee regarding any suspected misconduct, illegal activities or fraud, including any questionable accounting, internal accounting controls or auditing matters, or misconduct. Any person who has a concern regarding any misconduct by any GTx employee, including any GTx officer, or any agent of GTx, may submit that concern to: GTx, Inc., Attention Corporate Secretary, 3 North Dunlap Street, Memphis, Tennessee 38163. Employees may communicate all concerns regarding any misconduct to our Compliance Officer and/or the Audit Committee on a confidential and anonymous basis through GTx's "whistleblower" hotline, the compliance communication phone number established by GTx: 1-877-778-5463, or by filing an anonymous, confidential report through Report-it.com, a web-based online service for "whistleblower" communications accessed at [www.reportit.net](http://www.reportit.net). Any communications received through the toll free number or the online service is promptly reported to GTx's Compliance Officer, as well as other appropriate persons within GTx.

### **AUDIT COMMITTEE REPORT<sup>(1)</sup>**

The Audit Committee of the Board of Directors operates under a written charter approved by the Board of Directors, which is available on GTx's website ([www.gtxinc.com](http://www.gtxinc.com)) under "About GTx" at "Corporate Governance." The Audit Committee's charter specifies that the purpose of the Audit Committee is to assist the Board in its oversight of:

- the engagement and performance of the independent auditors;
- the quality and integrity of GTx's financial statements;
- the performance of GTx's internal audit function;
- GTx's system of internal controls; and
- compliance with legal and regulatory requirements.

In carrying out these responsibilities, the Audit Committee, among other things:

- monitors preparation of quarterly and annual financial reports by GTx's management;
- supervises the relationship between GTx and its independent registered public accountants, including:
  - having direct responsibility for their appointment, compensation and retention;
  - reviewing the scope of their audit services;
  - approving audit and non-audit services; and
  - confirming the independence of the independent registered public accountants;
- oversees management's implementation and maintenance of effective systems of internal and disclosure controls, including review of GTx's policies relating to legal and regulatory compliance, ethics and conflicts of interests and review of GTx's internal auditing program; and
- supervises the functions of our internal auditor, who is a GTx employee reporting to the Audit Committee, which include reviewing and testing the effectiveness of GTx's systems of internal and disclosure controls.

Management is responsible for: the preparation, presentation and integrity of GTx's financial statements; accounting and financial reporting principles; establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)); establishing and maintaining internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)); evaluating the effectiveness of disclosure controls and procedures; evaluating the effectiveness of internal control over financial reporting; and evaluating any change in internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting. GTx's internal auditor is responsible for testing such internal controls and procedures. The independent registered public accounting firm is responsible for performing an independent audit of GTx's financial statements in accordance with the

standards of the Public Company Accounting Oversight Board (United States) and to issue a report thereon, as well as expressing an opinion on the effectiveness of GTx's internal control over financial reporting. The Audit Committee's responsibility is to monitor and oversee these processes.

In connection with these responsibilities, the Audit Committee met with management, the internal auditor and the independent registered public accounting firm to review and discuss the audited financial statements, including a discussion of the quality and acceptability of GTx's financial reporting and controls. The Audit Committee also discussed with the independent registered public accounting firm the matters required by Statement on Auditing Standards No. 61, as amended (Communication with Audit Committee). The Audit Committee also received written disclosures from the independent registered public accounting firm required by Independence Standards Board Standard No. 1 (Independence Discussion with Audit Committees), and the Audit Committee discussed with the independent registered public accounting firm that firm's independence. The Audit Committee has also received both management's and the independent registered public accountant's reports on internal control over financial reporting.

Based upon the Audit Committee's discussions with management and the independent registered public accounting firm, and the Audit Committee's review of the representations of management and the independent registered public accounting firm, subject to the limitations on the role and responsibilities of the Audit Committee referred to above and in the Audit Committee Charter, the Audit Committee recommended that the Board of Directors include the audited financial statements in GTx's Annual Report on Form 10-K for the year ended December 31, 2007, filed with the Securities and Exchange Commission.

#### THE AUDIT COMMITTEE

Andrew M. Clarkson, Chair\*  
J. Kenneth Glass  
Timothy R. G. Sear

\* Mr. Clarkson has served as Chairman of the Audit Committee since March 2004; however, Mr. Clarkson is not standing for re-election at the 2008 Annual Meeting. The Board of Directors, upon the recommendation of the Nominating and Corporate Governance Committee, has appointed Mr. Glass, a current member of the Audit Committee, as Chairman of the Audit Committee, effective upon the expiration of Mr. Clarkson's term at the Annual Meeting. We currently expect that Dr. Mazanet, an independent director, will become a member of the Audit Committee in connection with Mr. Clarkson's departure from the Board.

(1) This Section is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filing of GTx under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

**PROPOSAL NO. 2**  
**RATIFICATION OF APPOINTMENT OF**  
**INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Audit Committee has selected Ernst & Young LLP as GTx's independent registered public accounting firm for the fiscal year ending December 31, 2008, and the Board of Directors has further directed that management submit the appointment of the independent registered public accounting firm for ratification by the stockholders at the Annual Meeting. Ernst & Young LLP has audited GTx's financial statements since its inception in 1997. A representative of Ernst & Young LLP is expected to be present at the Annual Meeting to make a statement if he or she so desires and to answer any appropriate questions.

Stockholder ratification of the appointment of Ernst & Young LLP as GTx's independent registered public accounting firm is not required by GTx's bylaws or other governing documents. However, the Board is submitting the appointment of Ernst & Young LLP to the stockholders for ratification as a matter of good corporate governance. However, the Audit Committee is not bound by a vote either for or against the proposal. The Audit Committee will consider a vote against the firm by the stockholders in selecting our independent registered public accounting firm in the future. Even if the stockholders do ratify the appointment, the Audit Committee in its discretion may direct the appointment of a different independent registered public accounting firm at any time during the year if it believes that such a change would be in the best interest of GTx and our stockholders.

Stockholder approval of this Proposal No. 2 requires a "FOR" vote from at least a majority of the shares represented and voting either in person or by proxy at the Annual Meeting on this Proposal No. 2 (which shares voting "FOR" also constitute at least a majority of the required quorum).

*On behalf of the Audit Committee, the Board of Directors recommends a vote "FOR" Proposal No. 2.*

**Independent Registered Public Accounting Firm's Fees**

The following table shows the fees paid or accrued by GTx for audit and other services provided by Ernst & Young LLP, GTx's independent registered public accounting firm, for the years ended December 31, 2006 and 2007.

Year	Audit Fees(1)	Audit-Related Fees(2)	Tax Fees(3)	All Other Fees	Total Fees
2006	\$447,092	--	\$28,541	--	\$475,633
2007	\$361,554	--	\$16,640	--	\$378,194

- (1) "Audit Fees" consist of fees for professional services provided in connection with the audit of our financial statements and review of our quarterly financial statements and audit services provided in connection with other statutory or regulatory filings.
- (2) "Audit-Related Fees" consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under "Audit Fees." There were no audit-related fees billed to GTx for services rendered during fiscal 2006 and 2007.
- (3) "Tax Fees" consist of fees associated with tax compliance, including tax return preparation.

**Pre-Approval Policies and Procedures**

Applicable SEC rules require the Audit Committee to pre-approve audit and non-audit services provided by our independent registered public accounting firm. On March 18, 2004, our Audit Committee began pre-approving all services by Ernst & Young LLP and has pre-approved all new services since that time.

The Audit Committee pre-approves all audit and non-audit services to be performed for GTx by its independent registered public accounting firm. The Audit Committee does not delegate the Audit Committee's responsibilities under the Securities Exchange Act of 1934 to GTx's management. The Audit Committee has delegated to the Chairman of the Audit Committee the authority to grant pre-approvals of audit services of up to \$25,000; provided that any such pre-approvals are required to be presented to the full Audit Committee at its next scheduled meeting. The Audit Committee has determined that the rendering of the services other than audit services by Ernst & Young LLP is compatible with maintaining Ernst & Young's independence.

**PROPOSAL NO. 3**  
**APPROVAL OF THE GTx, INC. 2004 EQUITY INCENTIVE PLAN, AS AMENDED**

Prior to GTx's initial public offering in 2004, GTx's Board of Directors and stockholders approved the GTx, Inc. 2004 Equity Incentive Plan (the "2004 Plan"). On March 6 2008, GTx's Board of Directors approved certain amendments to the 2004 Plan (the "Plan Amendments"), the effectiveness of which are subject to stockholder approval, to permit GTx to grant stock options that satisfy the requirements for deductibility under Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code"). As required by Section 162(m) of the Code, the Plan Amendments provide that no employee may be granted stock options and/or stock appreciation rights under the 2004 Plan covering more than 1,000,000 shares in any calendar year (the "162(m) Limit"). The 2004 Plan, as amended by the Plan Amendments (the "Amended 2004 Plan"), is otherwise identical to the 2004 Plan currently in effect. Stockholders should note that GTx is not requesting in this proposal that additional shares of GTx common stock be added to our share reserve for issuance under the Amended 2004 Plan.

Section 162(m) of the Code denies a tax deduction to any publicly-held corporation for compensation paid to certain "covered employees" in a taxable year to the extent that compensation paid to a covered employee exceeds \$1 million. If GTx does not seek approval of the Amended 2004 Plan at this Annual Meeting, it is possible that compensation attributable to stock options that are granted to covered employees after the date of this Annual Meeting, when combined with all other types of compensation received by a covered employee from GTx, may exceed this limitation in any given year. However, certain kinds of compensation, including qualified "performance-based compensation," are disregarded for purposes of the \$1 million deduction limitation. In accordance with Treasury Regulations issued under Section 162(m) of the Code, compensation attributable to stock options will qualify as performance-based compensation if (a) such awards are granted by a compensation committee comprised solely of "outside directors," (b) the plan contains a per-employee limitation on the number of shares for which such awards may be granted during a specified period, (c) the terms of the plan, including the per-employee limitation on grant size, are approved by the stockholders, and (d) the exercise price of the award is no less than the fair market value of the stock on the date of grant. Under applicable tax law, stock plans that were in existence prior to an initial public offering do not (absent a material modification of the plan) need to seek this stockholder approval until the first annual meeting at which directors are elected following the close of the third calendar year following the calendar year in which the corporation completes its initial public offering. For GTx, such deadline is this Annual Meeting. Therefore, in order for any new stock options that are granted to covered employees under the 2004 Plan after the Annual Meeting to be fully deductible to GTx under Section 162(m) of the Code, GTx's stockholders must approve the terms of the Amended 2004 Plan at the Annual Meeting. In addition, there is the possibility, under the Treasury Regulations, that if our stockholders do not vote to approve this Proposal No. 3, GTx will not be able to grant any stock awards to our covered employees until such time as a Section 162(m)-compliant plan is approved by our stockholders. Accordingly, GTx is requesting that its stockholders approve the Amended 2004 Plan.

GTx's Board of Directors believes that it would be in the best interests of GTx and its stockholders to be able to continue to grant stock awards to our covered employees and to allow for the tax deductibility of such awards. As described below in our Compensation Discussion and Analysis, equity compensation is a material element of our executive compensation program that we believe is necessary to retain executive officers and to incentivize them to build long-term stockholder value, and to align the interests of our executive officers with our stockholders. Accordingly, the Board of Directors recommends that you vote in favor of this Proposal No. 3. If this Proposal No. 3 is approved, the Amended 2004 Plan will then be immediately effective. If GTx's stockholders fail to approve this Proposal No. 3, the 2004 Plan as currently in effect will remain in effect, but no new stock awards will be made to any covered employees under the 2004 Plan after the Annual Meeting. Accordingly, the Board of Directors urges stockholders to vote "FOR" this Proposal No. 3.

Stockholder approval of this Proposal No. 3 requires a "FOR" vote from at least a majority of the shares represented and voting either in person or by proxy at the Annual Meeting on this Proposal No. 3.

***The Board of Directors recommends a vote "FOR" Proposal No. 3.***

**Material Features of the Amended 2004 Plan**

The material features of the Amended 2004 Plan are outlined below:

**General.** The Amended 2004 Plan provides for the grant of nonstatutory stock options, restricted stock awards, stock appreciation rights, phantom stock and other forms of equity compensation (which we refer to collectively as "stock awards" below) to employees (including officers), non-employee directors, and consultants. We have not granted incentive stock options under the 2004 Plan and we will not grant incentive stock options under the Amended 2004 Plan.

**Purpose.** The Board of Directors adopted the 2004 Plan to attract and retain the services of key employees (including officers), non-employee directors, and consultants, and to provide incentives for such persons to exert maximum efforts for the success of GTx and its affiliates.

**Share Reserve.** An aggregate of 1,500,000 shares of GTx common stock were originally reserved for issuance under the 2004 Plan. The number of shares reserved for issuance under the Amended 2004 Plan automatically increases annually on January 1st of each year, from 2005 until 2013, by five percent of the number of shares of GTx common stock outstanding on such date. However, the Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of GTx common stock will be increased on any such date. Pursuant to this authority, the Board of Directors designated that (i) no shares be added to the share reserve on January 1, 2005, (ii) no shares be added to the share reserve on January 1, 2006, (iii) two percent of the number of shares of GTx common stock outstanding on January 1, 2007, or 696,447 shares, be added to the share reserve on January 1, 2007 and (iv) 1,000,000 shares, or roughly three percent of the number of shares of common stock outstanding on January 1, 2008, be added to the share reserve on January 1, 2008. Accordingly, as of January 1, 2008, an aggregate of 3,196,447 shares of GTx common stock were reserved for issuance under the Amended 2004 Plan, awards covering 561,244 shares were outstanding under the Amended 2004 Plan, 5,000 shares had been issued upon the exercise of stock options granted under the 2004 Plan, and 2,630,203 shares remained available for issuance under the Amended 2004 Plan.

The following types of shares issued under the Amended 2004 Plan may again become available for the grant of new awards under the Amended 2004 Plan: shares issued under restricted stock awards that are repurchased or forfeited prior to becoming fully vested; shares withheld for taxes; shares used to pay the exercise price of an option in a net exercise; and previously acquired shares tendered to GTx to pay the exercise price of an option. In addition, shares subject to stock options that have expired or otherwise terminated without having been exercised in full may again become available for the grant of new awards under the Amended 2004 Plan. Shares issued under the Amended 2004 Plan may be previously unissued shares or reacquired shares bought on the market or otherwise.

**Administration.** The Board of Directors has the authority to administer the Amended 2004 Plan, but the Board of Directors may delegate authority to administer the Amended 2004 Plan to a committee, and has delegated authority to administer the Amended 2004 Plan to the Compensation Committee. Our Compensation Committee consists of at least two directors who are "non-employee directors" within the meaning of Rule 16b-3 under the Securities Exchange Act of 1934, as amended, and "outside directors" for purposes of Section 162(m) of the Code. Subject to the terms of the Amended 2004 Plan, the Board of Directors, the Compensation Committee or other authorized committee, referred to herein as the "plan administrator," determines recipients, grant dates, the numbers and types of equity awards to be granted and the terms and conditions of the equity awards, including the period of their exercisability and vesting. Subject to the limitations set forth below, the plan administrator also determines the exercise price of options granted, the purchase price for rights to purchase restricted stock and, if applicable, phantom stock and the strike price for stock appreciation rights. The plan administrator may also amend the terms of the Amended 2004 Plan and outstanding equity awards (see "—Duration, Amendment and Termination" below).

**Nonstatutory Stock Options.** Nonstatutory stock options are granted pursuant to nonstatutory stock option agreements. The plan administrator determines the exercise price for a nonstatutory stock option in its discretion, which generally will not be less than 100% of the fair market value of GTx common stock underlying the option on the date of grant (as fair market value is determined in accordance with the Amended 2004 Plan). Options granted under the Amended 2004 Plan vest at the rate specified in the option agreement, typically in three equal annual installments beginning on the third anniversary of the grant date.

The plan administrator determines the terms of nonstatutory stock options granted under the Amended 2004 Plan. As noted above, no employee may be granted stock options and/or stock appreciation rights covering more than 1,000,000 shares in any calendar year under the Amended 2004 Plan. The current 2004 Plan provides for no such limitation. Unless the terms of an optionee's nonstatutory stock option agreement provide otherwise, if an optionee's service relationship with GTx, or any of its affiliates, ceases due to disability or death, the optionee, or his or her beneficiary, may exercise any



vested options for up to 12 months in the event of disability, 18 months in the event of death and 24 months in the event of retirement, after the date such service relationship ends. If an optionee's relationship with GTx, or any affiliate of GTx, ceases for any reason other than disability, death or retirement, the optionee may exercise any vested options up to three months from cessation of service, unless the terms of the stock option agreement provide for earlier or later termination. Generally, stock options granted under the Amended 2004 Plan expire not later than ten years after the date of grant.

Acceptable consideration for the purchase of common stock issued upon the exercise of a nonstatutory stock option is determined by the plan administrator and may include cash, common stock previously owned by the optionee, a broker assisted exercise and the net exercise of the option.

Generally, an optionee may not transfer a nonstatutory stock option other than by will or the laws of descent and distribution unless the nonstatutory stock option agreement provides otherwise. However, an optionee may designate a beneficiary who may exercise the option following the optionee's death.

**Restricted Stock Awards.** Restricted stock awards are the issuance of shares of GTx common stock pursuant to the terms of a restricted stock award agreement. The purchase price for restricted stock awards must be at least the par value of the stock. The purchase price for a restricted stock award may be payable in cash or the recipient's past or future services performed or to be performed for GTx or any of its affiliates. Restricted stock awards may not be transferred other than by will or by the laws of descent and distribution.

**Stock Appreciation Rights.** Stock appreciation rights are rights to receive the appreciation value of a specified number of shares of GTx common stock, payable either in stock or cash, granted pursuant to stock appreciation rights agreements. The plan administrator determines the strike price for a stock appreciation right by which appreciation is measured, with such strike price generally not less than 100% of the fair market value of GTx common stock (as determined on the date of grant). A stock appreciation right granted under the Amended 2004 Plan vests at the rate specified in the stock appreciation rights agreement.

The plan administrator determines the term of stock appreciation rights granted under the Amended 2004 Plan. As noted above, no employee may be granted stock options and/or stock appreciation rights covering more than 1,000,000 shares in any calendar year under the Amended 2004 Plan. The current 2004 Plan provides for no such limitation. If an awardee's service relationship with GTx, or any of its affiliates, ceases due to disability or death, the awardee, or his or her beneficiary, may exercise any vested stock appreciation right up to three months or such longer or shorter period of time provided in the stock appreciation rights agreement. Different post-termination exercise periods may be provided in the stock appreciation rights agreement for specific terminations of service such as death, disability or retirement.

**Phantom Stock Awards.** Phantom stock awards are rights to be issued shares of GTx common stock, or their cash equivalent, pursuant to the terms of a phantom stock award agreement. A phantom stock award will require the payment of at least par value of the underlying shares of common stock to the extent required by applicable law. Payment of any purchase price may be made in any form of legal consideration acceptable to the plan administrator. Phantom stock awards may be subject to vesting based on continued service and/or achievement of performance milestones. Shares of common stock subject to a phantom stock awards are not issued until after such award vests. Rights to acquire shares under a phantom stock agreement may not be transferred other than by will or by the laws of descent and distribution.

**Other Equity Awards.** The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the award, the purchase price, if any, the timing of exercise and vesting and any repurchase rights associated with such awards. Unless otherwise specifically provided for in the award agreement, such awards may not be transferred other than by will or by the laws of descent and distribution.

**Changes in Control.** In the event of specified corporate transactions, all outstanding options and stock appreciation rights under the Amended 2004 Plan either will be assumed, continued or substituted for by any surviving or acquiring entity. If the surviving or acquiring entity elects not to assume, continue or substitute for such awards, such equity awards held by individuals whose service has not terminated prior to the effective date of the corporation transaction will become fully vested and exercisable prior to the effective date. All such equity awards will be terminated if not exercised prior to the effective date of the corporate transaction. GTx may assign the repurchase or forfeiture rights applicable to other forms of equity awards to the surviving or acquiring entity. If such repurchase or forfeiture rights are not assigned, then such equity awards will become fully vested prior to the effective date of the transaction. Following specified change

in control transactions, the vesting and exercisability of equity awards generally will be accelerated only if the awardee's award agreement so specifies. The standard form of stock option agreement under the Amended 2004 Plan provides for options to become fully vested and exercisable if an optionee is involuntarily terminated without cause or has a constructive termination, in either case, within twelve months after a change in control.

**Adjustments in Capitalization.** If any change is made in the stock subject to the Amended 2004 Plan or subject to any outstanding stock award without the receipt of consideration by GTx (such as through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other transaction not involving the receipt of consideration by GTx), the Amended 2004 Plan will be appropriately adjusted in the class(es) and maximum number of securities subject to the share reserve, the limit on the number of shares that may be issued as stock options to any one person in any calendar year for purposes of Section 162(m) of the Code and, if applicable, the annual evergreen, and the outstanding stock awards will be appropriately adjusted in the class(es) and number of securities and price per share of stock subject to such outstanding awards. The current 2004 Plan does not provide for adjustments with respect to the limit on the number of shares that may be issued as stock options to any one person in any calendar year for purposes of Section 162(m) of the Code since the current 2004 Plan does not provide for such a limit.

**Duration, Amendment and Termination.** The plan administrator may suspend or terminate the Amended 2004 Plan at any time; provided, however, that such suspension or termination may not impair the rights and obligations of stock awards granted prior to such suspension or termination without the written consent of the participant. The Amended 2004 Plan has no stated termination date. The plan administrator may also amend the Amended 2004 Plan or stock awards granted under the Amended 2004 Plan at any time; provided, however, that the amendment of a stock award may not impair the rights of the participant without the written consent of the participant. In addition, the plan administrator may amend an option to lower its exercise price or exchange an option for an option with a lower exercise price, another equity award, cash or any other valuable consideration or may take any other action that is treated as a repricing under generally accepted accounting principles. No amendment of the Amended 2004 Plan will be effective unless approved by GTx's stockholders to the extent such approval is necessary to satisfy applicable law. The Board of Directors may submit any other amendments to the Amended 2004 Plan for stockholder approval, including, but not limited to, further amendments intended to satisfy the requirements of Section 162(m) of the Code.

## **Federal Income Tax Information**

The following is a summary of the principal United States federal income taxation consequences to participants and GTx with respect to participation in the Amended 2004 Plan. This summary is not exhaustive, and does not discuss state, local or foreign tax laws.

**Nonstatutory Stock Options.** No taxable income is generally recognized by an optionee upon the grant of a nonstatutory stock option. Upon exercise, the optionee will recognize ordinary income equal to the excess of the fair market value of the purchased shares on the exercise date over the exercise price paid for those shares. Generally, GTx will be entitled to an income tax deduction in the tax year in which the optionee recognizes the ordinary income, subject to limitations imposed under applicable laws such as Section 162(m) of the Code, equal to the amount of ordinary income recognized by the participant at that time. When the optionee disposes of shares granted as a nonstatutory stock option, any difference between the sale price and the fair market value of the purchased shares on the exercise date, is treated as long-term or short-term capital gain or loss, depending on how long the optionee held those shares.

**Restricted Stock Awards.** A participant generally will not have taxable income upon grant, unless the participant was granted restricted stock and elects to be taxed at the time of grant. Absent such an election, a participant will recognize taxable ordinary income equal to the fair market value of the shares at the time they vest less the amount paid for the shares (if any). Generally, GTx will be entitled to an income tax deduction in the year in which the ordinary income is recognized by the participant equal to the amount of ordinary income recognized by the participant at that time.

**Stock Appreciation Rights.** No taxable income is generally recognized when a stock appreciation right is granted to a participant. Upon exercise, the participant will recognize ordinary income in an amount equal to the amount of cash received and the fair market value of any shares received. Generally, GTx will be entitled to an income tax deduction in the year in which the ordinary income is recognized by the participant equal to the amount of ordinary income recognized by

the participant at that time. If a participant received shares upon the exercise of a stock appreciation right, any additional gain or loss recognized upon any later disposition of the shares would be capital gain or loss.

**Phantom Stock Awards.** No taxable income is generally recognized upon receipt of a phantom stock award. In general, the participant will recognize ordinary income in the year in which the award vests and the shares (or cash value of the shares) are actually issued (or paid) to the participant in an amount equal to the fair market value of the shares (or cash) on the date of issuance. GTx will generally be entitled to an income tax deduction equal to the amount of ordinary income recognized by the participant at that time.

**Section 162(m) of the Code.** As stated above, stockholder approval of this Proposal No. 3 will constitute approval of the Amended 2004 Plan, including the 162(m) Limit, for purposes of Section 162(m) of the Code so that stock options granted (and stock appreciation rights, if granted) after the Annual Meeting under the Amended 2004 Plan will be eligible to qualify for full tax deductibility to GTx under Section 162(m) of the Code.

### Equity Compensation Plan Information

Please see the section of this proxy statement entitled "Equity Compensation Plan Information" for certain information with respect to compensation plans under which equity securities of GTx are authorized for issuance.

### Amended 2004 Plan Benefits

We cannot currently determine the benefits or number of shares subject to stock awards that may be granted in the future to executive officers, directors and employees under the Amended 2004 Plan since awards under the Amended 2004 Plan are determined by the plan administrator in its discretion. The following table sets forth information about awards granted under the 2004 Plan during the year ended December 31, 2007 to (i) GTx's "named executive officers," (ii) all current executive officers as a group (nine people), (iii) all non-employee directors as a group (eight people), and (iv) all non-executive employees (including all current officers who are not executive officers) as a group (approximately 60 people). On March 7, 2008, the last reported sales price of our common stock on the NASDAQ Global Market was \$14.21.

GTx, Inc. 2004 Equity Incentive Plan	
Name and Position	Number of Shares Subject to Stock Option Awards (#)
Mitchell S. Steiner, M.D., F.A.C.S. <i>Chief Executive Officer and Vice-Chairman of the Board of Directors</i> .....	—
Mark E. Mosteller, CPA <i>Vice President, Chief Financial Officer and Treasurer</i> .....	18,400
Marc S. Hanover <i>President and Chief Operating Officer</i> .....	—
Ronald A. Morton, Jr., M.D., F.A.C.S. <i>Vice President, Chief Medical Officer</i> .....	75,000
Henry P. Doggrell <i>Vice President, General Counsel and Secretary</i> .....	17,900
Executive Group .....	196,001
Non-Executive Director Group .....	—
Non-Executive Officer Employee Group .....	262,243

## EQUITY COMPENSATION PLAN INFORMATION

The following table provides certain information with respect to all of GTx's equity compensation plans in effect as of December 31, 2007:

Name	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
<b>Plan Category</b>			
Equity compensation plans approved by security holders.....	1,879,652	\$11.27	1,774,536(1)
Equity compensation plans not approved by security holders.....	43,367(2)	--(2)	--(3)
Total .....	1,923,019	\$11.27	1,774,536(1)(3)

- (1) In 1999, 2000, 2001 and 2002, we adopted the Genotherapeutics, Inc. Stock Option Plan, or the 1999 Plan, the GTx, Inc. 2000 Stock Option Plan, or the 2000 Plan, the GTx, Inc. 2001 Stock Option Plan, or the 2001 Plan, and the GTx, Inc. 2002 Stock Option Plan, or the 2002 Plan. On January 14, 2004, we adopted the GTx, Inc. 2004 Equity Incentive Plan, or the 2004 Plan, and the GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan, as amended, or the Directors' Option Plan, both of which became effective upon the consummation of GTx's initial public offering of its common stock. As of December 31, 2007, an aggregate of 1,630,203 shares of GTx common stock remained available for issuance under the 2004 Plan; however, the shares remaining available for issuance under the 2004 Plan is automatically increased annually on January 1st of each year until 2013 by five percent of the number of shares of common stock outstanding on such date unless the Board of Directors acts to decrease or eliminate any such increase. On October 31, 2007, the Board elected to increase the number of shares available for issuance under the 2004 Plan as of January 1, 2008 by 1,000,000 shares, or roughly three percent of the number of shares of GTx common stock outstanding at December 31, 2007, rather than the five percent set forth in the 2004 Plan. As of December 31, 2007, an aggregate of 144,383 shares of GTx common stock remained available for issuance under the Directors' Option Plan; however, the shares remaining available for issuance under the Directors' Option Plan is automatically increased annually on January 1st of each year until 2016 by the number of shares subject to options granted during the prior calendar year unless the Board of Directors acts to decrease or eliminate any such increase. On January 1, 2008, the number of shares available for issuance under the Directors' Option Plan increased by 55,667 shares.
- (2) Represents shares credited to individual director stock unit accounts as of December 31, 2007 under our Directors' Deferred Compensation Plan. There is no exercise price for these shares.
- (3) Does not include shares remaining available for issuance under our Directors' Deferred Compensation Plan. There are no limits on the number of shares issuable under our Directors' Deferred Compensation Plan, and the number of shares that may become issuable will depend on future elections made by plan participants.

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information as of March 1, 2008 (except as noted) regarding the beneficial ownership of our common stock by:

- each person, or group of affiliated persons, who is known by us to own beneficially five percent or more of our common stock;
- each of our directors and nominees for director;
- each of our named executive officers; and
- all our directors and executive officers as a group.

The number of shares owned and percentage ownership in the following table is based on 36,216,263 shares of common stock outstanding on March 1, 2008. Except as otherwise indicated below, the address of each officer, director and five percent stockholder listed below is c/o GTx, Inc., 3 North Dunlap Street, Memphis, Tennessee 38163.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options that are either immediately exercisable or exercisable within 60 days of March 1, 2008. We have also included shares credited to individual stock unit accounts under our Directors' Deferred Compensation Plan as of March 1, 2008. Amounts credited to individual stock unit accounts are payable solely in shares of GTx common stock, but such shares do not have current voting or investment power. Shares issuable pursuant to our Directors' Deferred Compensation Plan and shares issuable pursuant to the exercise of stock options that are either immediately exercisable or exercisable within 60 days of March 1, 2008 are deemed to be outstanding and beneficially owned by the person to whom such shares are issuable for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, we believe that the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them.

<u>Name and Address of Beneficial Owner</u>	<u>Beneficial Ownership</u>	
	<u>Number of Shares</u>	<u>Percent of Total</u>
<b>5% Stockholders:</b>		
Larry N. Feinberg .....	2,306,038 (1)	6.4%
200 Greenwich Avenue Greenwich, CT 06830		
FMR LLC .....	5,238,318 (2)	14.5%
82 Devonshire Street Boston, MA 02109		
<b>Directors and Named Executive Officers:</b>		
J. R. Hyde, III .....	10,951,833 (3)	30.2%
Mitchell S. Steiner, M.D., F.A.C.S. ....	4,862,147 (4)	13.4%
Marc S. Hanover .....	1,565,911 (5)	4.3%
Ronald A. Morton, Jr., M.D., F.A.C.S. ....	—	*
Henry P. Doggrell .....	275,848 (6)	*
Mark E. Mosteller .....	89,232 (7)	*
Michael G. Carter, M.D., Ch.B., F.R.C.P. ....	3,334 (8)	*
Andrew M. Clarkson .....	175,889 (9)	*
J. Kenneth Glass .....	55,221 (10)	*
Robert W. Karr, M.D. ....	15,447 (11)	*
Rosemary Mazanet, M.D., Ph.D. ....	37,977 (12)	*
John H. Pontius .....	2,775,609 (13)	7.7%
Timothy R. G. Sear .....	156,757 (14)	*
All Directors and Executive Officers as a group .....	17,618,922 (15)	48.0%

\* Represents less than 1% of the outstanding shares of our common stock.

(1) The indicated ownership is based solely on a Schedule 13G/A filed with the SEC on February 15, 2008, reporting beneficial ownership as of December 31, 2007. Mr. Feinberg has shared beneficial ownership with respect to 2,306,038 shares. Oracle Investment Management, Inc. (the

"Investment Manager") has shared beneficial ownership with respect to 1,588,997 shares. Mr. Feinberg is sole shareholder and president of the Investment Manager and the shares of common stock beneficially owned by the Investment Manager are also beneficially owned by Mr. Feinberg. Consequently, Mr. Feinberg's share ownership includes the shares beneficially owned by the Investment Manager. Mr. Feinberg is also the senior managing member of Oracle Associates, LLC ("Oracle Associates"). Each of Oracle Associates and the Investment Manager may exercise investment discretion over holdings of other funds and/or accounts (collectively, the "Oracle Funds"). The beneficial ownership reported by the Investment Manager includes shares held directly by it and also by certain of the Oracle Funds. Mr. Feinberg may be deemed to indirectly beneficially own shares of common stock, by virtue of the foregoing relationships, which are directly owned by the Investment Manager and various of the Oracle Funds.

- (2) The indicated ownership is based solely on a Schedule 13G/A filed with the SEC by the beneficial owners on February 14, 2008, reporting beneficial ownership as of December 31, 2007. According to the Schedule 13G/A, Fidelity Management & Research Company ("Fidelity"), a wholly-owned subsidiary of FMR LLC, was the beneficial owner of 5,238,318 shares of GTx's common stock in its capacity as investment advisor to various registered investment companies, referred to as the funds. The ownership of one of the funds, Fidelity Growth Company Fund, amounted to 2,296,397 shares. Edward C. Johnson 3d and FMR LLC, through its control of Fidelity, and the funds each has sole power to dispose of the 5,238,318 shares beneficially owned by the funds.
- (3) Includes 91,628 shares and 677,000 shares held by Pittco Associates, L.P. and Pittco Investments, L.P., respectively, entities controlled by Mr. Hyde, 1,459,673 shares held by trusts with respect to which Mr. Hyde may be deemed to have beneficial ownership, 1,393,077 shares held by Mr. Hyde's grantor retained annuity trusts and 216,462 shares held by Mr. Hyde's wife, of which Mr. Hyde disclaims beneficial ownership, and 6,849 shares issuable to Mr. Hyde pursuant to our Directors' Deferred Compensation Plan.
- (4) Includes 4,075,263 shares held by LD, Jr., LLC, an entity owned by Dr. Steiner and his wife jointly, 533,884 shares held by trusts with respect to which Dr. Steiner may be deemed to have beneficial ownership, 200,000 shares held by Dr. Steiner's grantor retained annuity trust and 26,500 shares held by Dr. Steiner's wife, of which Dr. Steiner disclaims beneficial ownership. Dr. Steiner has pledged all of the shares of stock owned by LD, Jr., LLC to Citibank to secure personal loans, although to date, there have been no borrowings against the loan by Dr. Steiner.
- (5) Includes 602,875 shares held by Equity Partners XII, LLC, an entity controlled by Mr. Hanover and 857,898 shares held by trusts of which Mr. Hanover is the trustee.
- (6) Includes 4,354 shares held by trusts with respect to which Mr. Doggrell may be deemed to have beneficial ownership, 114,350 shares held by a trust of which Mr. Doggrell is the co-trustee, 104,334 shares of common stock issuable upon the exercise of options held by Mr. Doggrell, and 1,000 shares of common stock held by Mr. Doggrell through an individual retirement account. Also includes 5,141 shares held by Mr. Doggrell's wife and 2,500 shares held in a joint account with Mr. Doggrell's adult child, of which Mr. Doggrell disclaims beneficial ownership.
- (7) Includes 71,668 shares of common stock issuable upon the exercise of options held by Mr. Mosteller and 7,282 shares held by Mr. Mosteller's wife.
- (8) Consists of 3,334 shares of common stock issuable upon the exercise of options held by Dr. Carter.
- (9) Includes 16,668 shares of common stock issuable upon the exercise of options held by Mr. Clarkson and 9,221 shares issuable to Mr. Clarkson pursuant to our Directors' Deferred Compensation Plan. Mr. Clarkson has 10,000 shares pledged to Regions Bank to secure personal loans. Mr. Clarkson has decided not to stand for re-election at the 2008 Annual Meeting.
- (10) Includes 16,668 shares of common stock issuable upon the exercise of options held by Mr. Glass and 6,553 shares issuable to Mr. Glass pursuant to our Directors' Deferred Compensation Plan.
- (11) Includes 11,557 shares of common stock issuable upon the exercise of options held by Dr. Karr and 2,890 shares issuable to Dr. Karr pursuant to our Directors' Deferred Compensation Plan.
- (12) Includes 16,668 shares of common stock issuable upon the exercise of options held by Dr. Mazanet and 6,849 shares issuable to Dr. Mazanet pursuant to our Directors' Deferred Compensation Plan.
- (13) Includes 16,668 shares of common stock issuable upon the exercise of options held by Mr. Pontius, 6,849 shares issuable to Mr. Pontius pursuant to our Directors' Deferred Compensation Plan, 2,628,050 shares held by trusts of which Mr. Pontius is the trustee, 21,520 shares held by trusts of which Mr. Pontius' wife is the trustee and 46,261 shares beneficially owned by Mr. Pontius' wife. Mr. Pontius disclaims beneficial ownership of the shares held by trusts of which his wife is trustee and shares beneficially owned by her.
- (14) Includes 6,000 shares of common stock issuable upon the exercise of options held by Mr. Sear and 6,423 shares issuable to Mr. Sear pursuant to our Directors' Deferred Compensation Plan.
- (15) Includes 126,003 shares beneficially owned by executive officers that are not named executive officers. For purposes of determining the number of shares beneficially owned by directors and executive officers as a group, any shares beneficially owned by more than one director or officer are counted only once.

## SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires our executive officers and directors and the holders of greater than 10% of our common stock to file initial reports of ownership and reports of changes in ownership with the SEC. Executive officers and directors are required by SEC regulations to furnish us with copies of these reports. Based solely on a review of the copies of these reports furnished to us and written representations from such executive officers, directors and stockholders with respect to the period from January 1, 2007 through December 31, 2007, we are not aware of any required Section 16(a) reports that were not filed on a timely basis.

Copies of the insider trading reports can be found at our corporate website at <http://www.gtxinc.com>, on our Investor Relations page, under the category "SEC Filings."

## COMPENSATION DISCUSSION AND ANALYSIS

### Introduction

Our compensation discussion and analysis discusses the total compensation for our Chief Executive Officer, Chief Financial Officer and the other three most highly compensated executive officers at December 31, 2007, or our "named executive officers." The compensation program for our named executive officers also applies to our other executive officers. Our compensation discussion and analysis describes our overall executive compensation philosophy, objectives and practices, as well as our decisions regarding executive compensation during 2007.

### What are the objectives of our executive officer compensation program?

The Compensation Committee believes that the compensation program for our named executive officers should be designed to attract, motivate and retain highly qualified executive officers responsible for the success of GTx and should be determined within a framework that rewards performance and aligns the interests of our executives with the interests of our stockholders. Within this overall philosophy, our Compensation Committee's objectives are to:

- Offer a total compensation program that enables GTx to attract, motivate and retain highly qualified and industrious executive officers. Since we and our competitors recruit from a limited pool of resources for individuals who are highly experienced, successful and well rewarded, the Compensation Committee's policy is to provide total compensation that is competitive with our peer companies within the biotech and pharmaceutical industry.
- Achieve an equitable balance in the compensation offered to each member of our executive team.
- Provide annual variable cash incentive awards that take into account the satisfaction of designated individual performance criteria based on our company performance goals.
- Make a significant portion of executive officer compensation dependent on GTx's long-term performance and on enhancing stockholder value by providing appropriate long-term, equity-based incentives and encouraging stock ownership.

### What is our executive compensation program designed to reward?

Our compensation program rewards our executive officers for achieving specified performance goals, building stockholder value and maintaining long-term careers with GTx. We reward these three aspects so that our executive team will make balanced annual and long-term decisions that we expect will result in consistent financial performance, scientific and product development innovations and the achievement of our strategic business objectives.

### What are the elements of our executive compensation program and why do we provide each element?

We have a straightforward compensation program. The three main elements are salary, annual bonuses and long-term equity incentives. We also provide our executive officers with a 401(k) retirement savings plan that matches employee contributions at the rate of 50% of the employee's contributions to the 401(k) plan not to exceed 6% of base salaries up to \$225,000. We may also, from time to time, offer certain additional benefits, such as transition benefits for new executive officers consisting of commuting expenses and temporary living expenses. Each of these elements helps us attract and retain executive officers.

Our Compensation Committee has not adopted any formal guidelines for allocating total compensation between equity compensation and cash compensation, but generally seeks to provide an overall executive compensation package designed to attract, motivate and retain highly qualified executive officers, to reward them for performance over time, and to align the interests of our executive officers with the interests of stockholders. Although equity compensation is an important component of our compensation program, particularly with respect to creating long-term stockholder value, the Compensation Committee has focused on adjusting executive officer base salaries to be in line with the median average salaries for comparable positions in our peer company group and offering cash bonus compensation pay incentives as the primary means to reward our named executive officers for the achievement of our larger company objective of moving product candidates through development and towards commercialization. Accordingly, we generally grant options to our

executive officers at a level lower than our peer company group average for comparable companies, but seek to attain total cash compensation in line with peer group medians.

#### *Elements of Executive Compensation*

**Base Salary.** We provide an annual salary to each executive officer as an economic consideration for each person's level of responsibility, expertise, skills, knowledge and experience, which we compare to other comparable companies within the biotech and pharmaceutical industry and adjust, as appropriate, to ensure that we will retain this expertise, skill and knowledge at our company.

**Bonus.** Cash incentive bonus compensation pay is part of our executive officers' annual compensation and one component of variable compensation. We may or may not award an annual bonus, and the amount of any award will vary, depending on each of the executive officer's successful fulfillment of individual performance criteria (which are based on our overall annual company goals) established by the Compensation Committee.

**Long-term Incentives.** We currently provide long-term incentives solely in the form of stock options. Long-term incentives are a form of variable compensation in that the number of options granted is discretionary and the amount of any income earned is completely dependent upon, and varies with, our stock price over the option term. We offer stock options as an incentive to build long-term stockholder value, to align the interests of executive officers and stockholders, and to retain executive officers through what we hope will be long-term wealth creation in the value of their stock options, which have vesting provisions that encourage continued employment. Our executive officers are motivated by the potential appreciation in our stock price above the exercise price of the stock options. With respect to encouraging continued employment, stock option grants to our executive officers typically require the executive to remain a GTx employee for a three year period before the options even begin vesting. In other words, the Compensation Committee believes it is important to tie the long-term benefit potentially realizable by the executive to a long-term commitment to GTx. We also encourage stock ownership which we regard as important for commitment, engagement and motivation. We may refine our long-term incentive strategy should it be in the interests of stockholders so that we can continue to attract and retain the highly skilled talent required to execute our business strategy:

**Benefits.** Benefits offered to GTx's executive officers serve a different purpose than do the elements of total compensation. In general, benefits provide a safety net of protection against the financial catastrophes that can result from illness, disability or death. In addition to the benefits offered to the general employee population, our executive officers receive life insurance coverage equal to two times the executive officer's annual salary (compared to the \$50,000 of life insurance coverage offered to the general employee population of GTx). The Compensation Committee evaluated the cost of providing such additional life insurance coverage and found it to be immaterial in relation to the incremental benefit to be offered to our executive officers. In addition, we provide an Executive Supplemental Long Term Disability Plan to increase the income replacement insurance for executive officers in the case of disability. The Executive Supplemental Long Term Disability Plan provides income replacement equal to 75% of base salary to Mr. Hanover, our Chief Operating Officer, and all Vice Presidents, and income replacement equal to 71% of base salary to Dr. Steiner, our Chief Executive Officer, compared to income replacement of 60% of base salary, not to exceed \$10,000 per month, offered to the general employee population of GTx.

**Perquisites.** Except for the additional benefits provided to its executive officers described above, GTx does not generally provide its executive officers with any other perquisites and benefits that differ from what are provided to GTx employees generally. To date, the Compensation Committee has not considered such additional perquisites and benefits as a necessary element of GTx's executive compensation program. However, GTx may, from time to time, offer certain perquisites and benefits to its executive officers, such as relocation and temporary housing benefits in connection with the hiring of a new executive officer. For example, in 2007, we paid Dr. Morton's temporary living expenses during his relocation to Memphis, Tennessee.

**Employment Agreements.** Each of our executive officers has entered into a written employment agreement with GTx. These employment agreements provide for base salary and the other customary benefits as described above, as well as "double trigger" post-termination change of control payments equal to one year's base salary as described under "—Post-Employment Compensation" below. Each employment agreement is terminable by either the executive officer or us at any time. Our employment agreements with Dr. Steiner, Mr. Mosteller, Mr. Hanover and Mr. Doggrell were approved by our Board of Directors and entered into immediately prior to our initial public offering in February 2004. We entered into a



similar employment agreement with Dr. Morton in April 2007 when he began his employment with GTx. Our employment agreements with our named executive officers all have substantially similar terms except for salary and certain non-competition obligations. In this regard, each of Dr. Steiner, Mr. Hanover and Dr. Morton has agreed not to compete with us (including by soliciting our employees for alternative employment) during the term of their employment and for a period of two years after their employment ends (if we undergo a change of control, these two-year periods will be shortened to one year). These provisions help protect GTx from the resignations of these named executive officers from GTx and their using the essential scientific knowledge gained while working for GTx to compete against us.

*Post-Employment Compensation.* The employment agreements with our named executive officers contain cash change of control payments that are structured on a "double-trigger" basis, meaning that before a named executive officer can receive cash change of control payments: (1) a change of control must occur and (2) within six months of such change of control, the named executive officer's employment must be terminated for good reason or without cause. These provisions were included to motivate our named executive officers to act in the best interests of the stockholders by removing the distraction of post change in control uncertainties faced by the named executive officers with regard to his continued employment and compensation. Our Compensation Committee believes that a "double-trigger" change of control provision providing for payments equal to one year's base salary is attractive to maintain continuity and retention of key management personnel and is consistent with GTx's compensation philosophy. In addition, under our stock option plans that were adopted prior to our initial public offering and pursuant to which we continue to grant stock options to executives, a change of control will automatically trigger the vesting of all options granted under these plans. Our 2004 Equity Incentive Plan, which became effective in connection with our initial public offering and pursuant to which we also grant options to our executive officers, provides for automatic vesting of unvested options only if the executive officer is not retained in the same or comparable position within twelve months following a change of control, or if the surviving or acquiring entity refuses to assume or substitute for the options. These provisions are intended to remove any personal disincentive an executive officer may have to a change of control transaction which, if appropriately assessed on its merits, may prove beneficial to GTx and its stockholders.

#### **How do we determine the amount for each element of executive officer compensation?**

*Process.* In its process for deciding the levels at which to compensate our named executive officers, the Compensation Committee receives and reviews competitive compensation data to determine the 25th percentile, median, and 75th percentile of (1) average salary, (2) target annual cash compensation (i.e., salary + target bonus), (3) long-term incentive compensation, and (4) target total direct compensation (i.e., salary + target bonus + long-term incentives) for executive officer positions among a group of peer companies and to assess how similar compensation arrangements for GTx executive officers compare to its peers. A base salary range between the 25th percentile and the 75th percentile of our peer group is consistent with what the Compensation Committee believes is competitively reasonable and appropriate for the named executive officers, although the Compensation Committee's current objective is to establish base salary and provide incentive bonus compensation targets for GTx's executive officers that are generally consistent with the median compensation levels among our peer industry group. Long-term incentive compensation is provided in the form of stock options with annual grants typically below average grants provided to comparable executives by our peer group, reflecting the Compensation Committee's belief in the growth potential of our common stock warranting the grant of fewer numbers of options. However, the Committee does not tie cash compensation to potential values realizable from option grants to measure total target direct compensation as a means to determine the option grants it authorizes, and looks at this data from our peers only as another guideline for assessing how our executive compensation program compares to our peer group in an effort to ensure that our compensation program remains competitive. In determining executive compensation, the Compensation Committee may also consider other relevant factors in determining appropriate compensation levels for each executive officer in order to ensure that base salaries, bonus compensation targets and stock option awards are fair and equitable among the executive team members and to appropriately reflect the expected contributions to GTx by each executive officer. For example, in late 2006, when the Compensation Committee established base salaries and bonus compensation targets for its named executive officers for 2007 (and again in late 2007, when it similarly established base salaries and bonus compensation target awards for 2008), although the Compensation Committee relied primarily on its review of competitive compensation data from our peer group companies in setting base salaries and bonus compensation targets, the Compensation Committee adjusted base salaries and bonus compensation target awards to retain an element of fundamental fairness among the executive officer team members. In this regard, recognizing that it was necessary to pay a base salary in excess of the peer group median to attract the services of a skilled physician of Dr. Morton's caliber as our new Chief Medical Officer, the Compensation Committee decided to also adjust the base salary to be paid to Mr. Hanover for 2008 to an amount in excess of the median salaries for a comparable position in our peer group, reflecting the

Compensation Committee's view that Mr. Hanover's services to GTx warrant his being paid a base salary in excess of Dr. Morton.

*Use of compensation consultants.* In 2006, the Compensation Committee retained Mercer Human Resource Consulting, or Mercer, to assist with the Committee's analysis and determination of the 2007 compensation of our executive officers. The Committee was informed that Mercer also was retained by GTx to assist it in evaluating salary ranges for various employee levels within GTx, but since the Compensation Committee retained the sole power and authority to establish the nature and scope of Mercer's engagement, set the fee to be paid to Mercer and to terminate Mercer's engagement, the Compensation Committee determined that its relationship with Mercer was sufficiently independent of the services Mercer was rendering for GTx. The Compensation Committee directed Mercer to review GTx's executive compensation program and to recommend changes as deemed appropriate to ensure that GTx's executive compensation program provides reasonable and competitive pay opportunities that are aligned with key business objectives and best practices. At the direction of the Compensation Committee, Mr. Mosteller and Mr. Doggrell discussed with Mercer the duties of each executive officer of GTx and provided Mercer with information requested by Mercer as part of its evaluation of GTx's executive compensation programs and policies. The information included each executive officer's title, direct and indirect reports, salary, bonus, if any, option grants and benefits for the preceding three-year period. The Compensation Committee has supplemented this information with similar more current compensation data obtained through an independent web-based compensation data service, which it utilized for the purpose of determining base salaries, bonus compensation targets and stock option awards for its named executive officers for 2008.

*Identification of peer group.* Based on industry peer group data available to Mercer, including data from proxy filings by representative companies available to Mercer in 2006, Mercer selected from its proprietary database and two other similar databases available to Mercer the following peer group of 23 biopharmaceutical companies as a representative industry group most similar to GTx based on their number of employees, market capitalization and stage of development:

Altus Pharmaceuticals, Inc.	Antigenics, Inc.	Ariad Pharmaceuticals, Inc.
Biocryst Pharmaceuticals, Inc.	Cell Genesys, Inc.	Coley Pharmaceutical Group
CombinatoRx, Inc.	Cytokinetics, Inc.	Dendreon Corp.
Dov Pharmaceutical, Inc.	Hollis-Eden Pharmaceuticals	Icagen, Inc.
Idenix Pharmaceuticals, Inc.	Inhibitex, Inc.	Keryx Biopharmaceuticals, Inc.
Myogen, Inc.	Neopharm, Inc.	Neurogen Corp.
Nuvelo, Inc.	Onyx Pharmaceuticals, Inc.	Progenics Pharmaceutical, Inc.
Renovis, Inc.	Rigel Pharmaceuticals, Inc.	

*Comparison of GTx executive compensation to peer group and recommendations.* In 2006, Mercer reviewed base salaries, bonus compensation and equity incentives provided by each company within the peer group it selected for 2006, and then ranked the compensation provided to GTx executive officers. The results of Mercer's review are summarized below:

- the base salaries for GTx executive officers were found to be below the peer group 50th percentile (median) levels for our then executive officers but, according to Mercer, fell within a competitive range of the peer group median;
- the total cash compensation, consisting of salary plus cash bonuses, was well below the peer group 25th percentile for our then executive officers, reflecting the then existing historic lack of annual cash incentive award opportunities for GTx executive officers; and
- total direct compensation (total cash compensation plus annualized grant date value of long-term equity incentives) was below the peer group 25th percentile for our then executive officers and approximately 91% of the peer group 25th percentile when Dr. Steiner and Mr. Hanover were excluded from the comparison (Dr. Steiner and Mr. Hanover were excluded from the comparison due to the Compensation Committee's determination in 2006 that, as co-founders of GTx with substantial stock holdings, no additional option grants were at that time warranted).

Mercer suggested that the Compensation Committee continue to manage base salaries for GTx's executive officers within a competitive range of market median levels for GTx's peer group, and consider implementing an annual cash bonus plan for executive officers and other key employees to strengthen the link between pay and performance and to reward the

attainment of annual company goals in support of long-term stockholder value creation. Mercer also suggested that the Compensation Committee continue to utilize long-term incentive awards through grants of stock options or other equity awards to align the interests of GTx's executive officers, including, if desired, the co-founders, with those of its stockholders. Based on Mercer's recommendations and the Compensation Committee's desire to offer competitive and fair compensation, the Compensation Committee adopted in 2006 the GTx Executive Bonus Compensation Plan, commencing as of the calendar year 2007, as described in more detail below.

*How compensation or amounts realizable from prior compensation are considered.* The Compensation Committee reviews the current value of shares owned and the current value of exercisable and unvested stock options as part of its annual review of executive officer stock option awards, and determines the amount of the annual stock options awards for each group of executives at GTx based, in part, on this historical information and the Compensation Committee's determination of the potential dilution caused by such awards and the incentives provided by such awards for the executive officers to create long-term value. Recognizing that there is a tradeoff between utilizing option grants as long-term incentive awards for our executive officers and increasing the prospect of stockholder dilution, the Committee strives to strike a balance between providing meaningful and potentially valuable incentives without creating a potential for excessive stockholder dilution. The Compensation Committee looks at data from its peers to measure the percentage relationship of all vested and unvested options issued to GTx employees to total GTx shares outstanding, to make certain that this percentage relationship is at or below the average median percentages based on similar information regarding its peers. The amount of past cash compensation realized, including annual bonus awards and amounts realized from prior stock option awards, is generally not a significant factor in the Compensation Committee's consideration of current stock option awards, since the Compensation Committee believes annual stock option awards continue to keep the executives focused on our long-term performance.

*Chief Executive Officer and Chief Operating Officer involvement in executive compensation decisions.* Our Compensation Committee retains the authority for establishing all matters with respect to the compensation of our executive officers (although our Compensation Committee may recommend to the full Board of Directors that it take action with respect to such compensation matters). Dr. Steiner, however, provides to the Compensation Committee an annual performance review of each of our other executive officers which is considered by the Compensation Committee in its determination of compensation for such officers. Dr. Steiner and Mr. Hanover also recommend to the Compensation Committee the number of stock options to be granted to our other executive officers, subject to guidance provided to them by the Chairman of the Compensation Committee and consistent with the data supplied by the Committee's compensation consultants regarding GTx's peer group. It is within the prerogative of the Compensation Committee to approve, modify or disapprove any recommendations for grants of options to our executive officers. Dr. Steiner and Mr. Hanover also provide recommendations to the Compensation Committee with respect to the specific performance goals to be achieved to receive executive bonus compensation under our Executive Bonus Compensation Plan. After receipt of the recommendations of Dr. Steiner and Mr. Hanover and the Committee's review of information obtained from our peer group compensation data and other relevant factors, the Compensation Committee meets in executive session with no members of management present to discuss and determine appropriate base salaries, bonus compensation target awards and stock option grants for each executive officer of GTx.

#### **What is our analysis of the compensation for our named executive officers in 2007?**

*Salary.* As stated above, in determining base salaries, the Compensation Committee seeks to compare the base salaries of our executive officers against the salaries for comparable positions paid by companies in GTx's peer group. Within this comparison group, the Compensation Committee makes comparisons to executive officers at comparable levels of experience, who have comparable levels of responsibility and expected levels of contribution to our performance. In setting base salaries for 2007, the Compensation Committee relied primarily on the compensation data made available to it by Mercer, and it approved increases from 2006 base salaries for the executive officers for 2007 to amounts it believed would result in salaries being at or near the median base salaries for comparable executive positions at our peer group companies and reasonably consistent with the average percentage increase in salaries by its peers. The salary increases from 2006 also reflect the Compensation Committee's belief that GTx should retain an equitable balance in the compensation of its executive officers. Accordingly, each named executive officer (other than Dr. Morton) received a 5% salary increase from 2006. In 2007, the Compensation Committee also approved compensation agreements for two new executive officers, including Dr. Morton, at base salaries in excess of the median average salaries paid by GTx's peers, reflecting the level of competition among companies in GTx's industry to attract and retain talented personnel. A table reflecting the increase from 2006 base salaries is set forth below:

Name	2006 Base Salary	2007 Base Salary
Mitchell S. Steiner, M.D., F.A.C.S.	\$425,000	\$446,250
Mark E. Mosteller	\$235,000	\$246,750
Marc S. Hanover	\$292,000	\$306,600
Ronald A. Morton, Jr., M.D., F.A.C.S.	—	\$410,000
Henry P. Doggrell	\$253,000	\$265,650

*Annual Bonus Awards.* Based on Mercer's recommendation, the Compensation Committee established the Executive Bonus Compensation Plan to reward executive officers for their role in achieving specified performance goals. All of our named executive officers are eligible to participate in the Executive Bonus Compensation Plan. Payments of bonus awards are based solely on the attainment of pre-established, objective performance goals that are established by the Compensation Committee. Bonus compensation payments are calculated as a percentage of base salary based on information supplied by Mercer that chief executive officers are typically paid bonuses ranging from 45% to 55% of their salaries and other executives received bonuses in the range of 30% to 40% of base salaries. For 2007, the Committee determined that it would set maximum bonus payments at 40% of base salary for our Chief Executive Officer, Dr. Steiner, 35% of base salary for Mr. Hanover, our Chief Operating Officer, and 30% of base salaries for all Vice Presidents, since the Committee felt that bonus payments on the lower end of Mercer's recommendation was more appropriate for a company that is not yet in a position to commercialize its products.

The performance goals under the Executive Bonus Compensation Plan are based on approved corporate objectives for the year, and form the basis for the bonus compensation targets of Dr. Steiner and Mr. Hanover. These performance goals are then tailored to the specific performance criteria to be achieved by each other executive officer in support of attaining the designated corporate objectives. The Compensation Committee approves the objective performance goals and specific criteria, including the weight attributable to each objective, for each executive officer after reviewing recommendations supplied to the Compensation Committee by Dr. Steiner and Mr. Hanover, who present the Committee with stretch goals for the coming year. The objective criteria may include achievement of the operating budget for GTx as a whole or of a business unit of GTx, continued innovation in development and progress towards commercialization of our product candidates, timely development of new product candidates or processes, development and implementation of successful marketing and commercialization strategies for our product candidates, implementation of financing strategies and establishment of strategic development alliances with third parties, as well as meeting pre-clinical or clinical milestone objectives. The Compensation Committee then evaluates after the end of the calendar year the attainment of the corporate objectives and the extent to which each such executive officer met his or her specified performance criteria to support the corporate objectives. While in some cases the performance objectives for the executive officers can overlap, the Compensation Committee grades each executive officer's performance individually and considers factors that may justify awarding different amounts for the same criteria, if, for example, one executive has more direct control over a particular matter than another.

In 2007, our company performance goals included:

- initiating an Ostarine™ Phase II clinical trial for cancer cachexia under an Investigational New Drug, or IND, application filed with the FDA;
- enrolling the Ostarine™ Phase II clinical trial for cancer cachexia initiated under an IND application filed with the FDA;
- completing the ACAPODENE® Phase III clinical trial for the treatment of multiple side effects of androgen deprivation therapy, or ADT, and resolving all data discrepancies in order for the independent database manager to submit the final trial data in the manner proscribed by the requirements of the FDA to determine the outcome of the clinical trial;
- concluding a successful collaboration with a third party for our SARM product candidates;
- attracting and hiring certain specific senior management level employees to fill specified critical roles;
- developing additional SARM compounds for clinical trials and developing at least one new molecule class;
- initiating New Drug Application, or NDA, preparation for ADT; and

- maintaining or lowering budgeted expenditures for fiscal 2007:

Under the Executive Bonus Compensation Plan, the Compensation Committee established specific performance criteria for each executive officer that were aligned with the goals set forth above. At the Compensation Committee meetings held in July 2007 and late October 2007, Dr. Steiner and Mr. Hanover reviewed with the Compensation Committee the status of the objective performance goals established under our Executive Bonus Compensation Plan for each of our executive officers and the likelihood that the performance goals would be fulfilled by year end 2007 so the Committee members could monitor the progress of the executives in fulfilling their specific performance goals, which helps Committee members better understand the likelihood of whether various corporate objectives would be attained during the year. The bonus compensation awards, if earned, are paid during the first quarter of the next succeeding fiscal year, after the Compensation Committee has reviewed and approved year-end data and other information necessary to establish the awarding of the bonuses. The Compensation Committee establishes performance goals intended to reflect tasks beyond what should be reasonably expected of an executive officer during the particular calendar year, which, if attained, justify the payment of additional compensation.

The performance goals and the relative weighting of each such goal for Dr. Steiner and our other named executive officers is set forth in the table below. Each of our executive officers had some of the same specific performance goals as Dr. Steiner which they were required to achieve to be eligible for bonus compensation payments for 2007, although the weightings were different, reflecting the impact each executive officer was expected to have on the specified targets, and in some instances, other specific goals were substituted for one or more of Dr. Steiner's goals in line with the particular executive's duties and responsibilities. For example, the performance goals for Mr. Mosteller, our Chief Financial Officer, did not include preclinical and key hiring objectives, but did include two specific objectives pertaining to our Information Technology department, for which Mr. Mosteller is responsible, and a greater weighting for the budget in line with Mr. Mosteller's duties as our Chief Financial Officer. Similarly, the performance objectives for 2007 for Mr. Doggrell, our General Counsel, excluded the preclinical and hiring objectives, but included eight specific objectives pertaining to the Legal department, for which he is responsible.

Performance Goal Category	Weighting for Each Named Executive Officer				
	Dr. Steiner	Mr. Mosteller	Mr. Hanover	Dr. Morton	Mr. Doggrell
Regulatory affairs <sup>(1)</sup>	20%	5%	15%	20%	5%
Clinical <sup>(2)</sup>	20%	5%	15%	20%	5%
Preclinical <sup>(3)</sup>	5%	*	*	*	*
Senior management and key position hiring <sup>(4)</sup>	10%	*	10%	*	*
Budget <sup>(5)</sup>	10%	30%	15%	5%	10%
Business development <sup>(6)</sup>	10%	10%	15%	*	10%
Audit/Sarbanes-Oxley requirements <sup>(7)</sup>	10%	35%	10%	*	15%
NDA preparation and documentation <sup>(8)</sup>	10%	5%	10%	*	15%
Investor relations <sup>(9)</sup>	5%	*	5%	*	*
Information technology <sup>(10)</sup>	*	10%	5%	*	*
Legal <sup>(11)</sup>	*	*	*	*	40%
Medical affairs <sup>(12)</sup>	*	*	*	20%	*
Project management <sup>(13)</sup>	*	*	*	20%	*
Marketing support <sup>(14)</sup>	*	*	*	5%	*
Reimbursement support <sup>(15)</sup>	*	*	*	5%	*
Manage key opinion leader, or KOL, activities <sup>(16)</sup>	*	*	*	5%	*

(1) Includes making the IND submission for the Ostarine™ Phase II clinical trial for cancer cachexia and fulfilling certain objectives pertaining to FDA-related initiatives.

(2) Includes fulfilling specified objectives pertaining to the ACAPODENE® Phase III clinical trial and initiating the Phase II clinical trial of Ostarine™ for cancer cachexia.

(3) Includes successfully completing certain preclinical testing for preclinical compounds to fulfill specified criteria.

(4) Includes successfully hiring certain qualified persons for specific senior management and other key positions.

(5) Includes meeting stated financial targets approved by the Board and managing cash, employee benefits and payroll.

(6) Includes successfully entering into collaborative relationships and concluding a financing.

- (7) Includes obtaining our independent auditor attestation, the timely filing of required annual and quarterly reports and satisfying Sarbanes-Oxley compliance requirements.
- (8) Includes preparing final reports for preclinical testing and clinical trials for ACAPODENE® and drug product and manufacturing data in a format to allow for submission in an NDA to be filed with the FDA.
- (9) Includes adding analyst coverage and broadening relationships with a specified number of key potential biotech investors.
- (10) Includes establishing a disaster recovery plan and resources and maintaining corporation information systems at a designated high level of efficiency.
- (11) Includes establishing a corporate compliance department and program, managing our patent portfolio and providing specified levels of support for clinical operations.
- (12) Includes developing a publication strategy and establishing and managing relationships with clinical trial investigators.
- (13) Includes developing and managing project management activities for designated company project teams.
- (14) Includes providing specific support for marketing regarding disease states relative to product candidates in clinical trials.
- (15) Includes meeting with and educating physicians who manage drug formularies about medical issues pertaining to certain medical indications.
- (16) Includes managing all relationships with key opinion leaders of GTx, including overseeing KOL and advisory board activities.

In February 2008, the Compensation Committee conducted a final review of each executive officer's target bonus compensation criteria for 2007, and, based on their review, made the following determinations:

- Dr. Steiner had satisfied approximately 72% of his personal performance goals, resulting in incentive bonus compensation of approximately 29% of his 2007 base salary, or \$128,520;
- Mr. Mosteller had satisfied approximately 90% of his personal performance goals, resulting in incentive bonus compensation of approximately 27% of his 2007 base salary, or \$66,623;
- Mr. Hanover had satisfied approximately 72% of his personal performance goals, resulting in incentive bonus compensation of approximately 25% of his 2007 base salary, or \$77,263;
- Dr. Morton had satisfied approximately 80% of his personal performance goals, and, after prorating the bonus amount to reflect his partial year of employment with GTx, he received incentive bonus compensation of approximately 17% of his 2007 base salary, or \$71,094; and
- Mr. Doggrell had satisfied approximately 83% of his personal performance goals, resulting in incentive bonus compensation of approximately 25% of his 2007 base salary, or \$66,147.

*Long-term Incentive Compensation.* As stated above, in determining the amount of each stock option grant, the Compensation Committee reviews the current value of shares owned and the current value of exercisable and unvested stock options as part of its annual review of executive officer stock option awards, and determines the amount of the annual stock options awards for each group of executives at GTx based, in part, on this historical information and the Compensation Committee's determination of the potential dilution caused by such awards and the incentives provided by such awards for the executive officers to create long-term value. The Compensation Committee also takes into account the number of options to be granted to an executive officer relative to grants to other executive officers and grants to similar officers within the GTx peer group. The Compensation Committee has continued to follow a conservative approach to issuing stock option awards to our executive officers, issuing annual option grants which are lower than peer average equity based awards during the same period. In 2006, the Compensation Committee approved option grants covering 25,000 shares of GTx common stock for each of Mr. Doggrell and Mr. Mosteller, which grants were effective on January 1, 2007. Because of the significant share ownership of Dr. Steiner and Mr. Hanover, the Compensation Committee elected not to award stock options or other equity-based compensation to either Dr. Steiner or Mr. Hanover for 2007, relying solely on their respective salaries, potential bonuses, and their own stock holdings in GTx to adequately compensate and motivate them. Also, in 2007, Dr. Morton received a grant of 75,000 options when he joined us as our Chief Medical Officer. The grant of options, as well as his base salary and temporary living expense reimbursements for 2007, was the result of a negotiated employment agreement between GTx and Dr. Morton, and this negotiated compensation, together with the target bonus compensation he receives as an executive officer of GTx, reflects compensation that the Committee deems appropriate for an executive of Dr. Morton's caliber.

## 2008 Compensation

In October 2007, the Compensation Committee began its evaluation of executive compensation for the current fiscal year. The Compensation Committee reviewed compensation data developed by Equilar, Inc., or Equilar, a web-based independent executive compensation firm, which compensation data included base salary, bonus compensation and equity and/or stock option awards received by the chief executive officer, president and other executive officers of many of the same pharmaceutical and biotech companies selected by the Compensation Committee for its review of comparable industry data by Mercer in 2006.

The compensation data developed by Equilar for the Compensation Committee was derived from 18 of the original peer group companies established through the Mercer engagement in 2006. The Compensation Committee refined the original Mercer peer group list to adjust for mergers and acquisitions and selected 18 companies from the 2006 Mercer list to request current compensation data from Equilar's database. The following companies comprised the peer group used by the Compensation Committee for establishing 2008 executive officer compensation:

Antigenics, Inc.	Dov Pharmaceutical, Inc.	Neurogen Corp.
Cell Genesys, Inc.	Hollis-Eden Pharmaceuticals, Inc.	Nuvelo, Inc.
Coley Pharmaceutical Group, Inc.	Icagen, Inc.	Onyx Pharmaceuticals, Inc.
CombinatoRx, Inc.	Idenix Pharmaceuticals, Inc.	Progenics Pharmaceuticals, Inc.
Cytokinetics, Inc.	Inhibitix, Inc.	Renovis, Inc.
Dendreon Corp.	Keryx Biopharmaceuticals, Inc.	Rigel Pharmaceuticals, Inc.

During a series of meetings in late 2007, the Compensation Committee utilized the data from Equilar for the peer group companies listed above to evaluate the base salaries, target bonus levels and stock option awards for each of GTx's executive officers. The Compensation Committee adjusted the compensation amounts in Equilar's data by a reasonable inflation factor to project peer compensation levels for calendar year 2008, and then established compensation for GTx's executive officers for 2008 which are projected to fall within the median salary ranges identified in our competitive analysis. Salaries in excess of the median peer group salary targets were approved by the Committee for Dr. Morton, GTx's Chief Medical Officer, reflecting the requirement of our industry to pay highly competitive compensation to attract persons with Dr. Morton's unique urologic expertise and skills, and Mr. Hanover, GTx's Chief Operating Officer, whose position with us, the Committee believes, warrants his being paid a base salary in excess of Dr. Morton.

At the February 2008 Compensation Committee meeting, bonus criteria under the Executive Bonus Compensation Plan was established and approved by the Compensation Committee for 2008, which, if achieved, will provide incentive bonus compensation pay of up to 50% of 2008 base salary for Dr. Steiner, 45% of 2008 base salary for Mr. Hanover, and 30% of 2008 base salary for the rest of our executive officers. Bonus compensation targets were increased to 50% for Dr. Steiner, consistent with the average bonus compensation payments received by chief executive officers of GTx's peer group companies. Mr. Hanover's bonus compensation target of 45% of base salary is above his peer group average, but the Compensation Committee believes that this is warranted given Mr. Hanover's importance to GTx. The Compensation Committee determined to keep bonus targets at 30% for the other executive officers for 2008 until we begin to transition from essentially a research and development company to a company conducting research and development and commercializing its discovery products. The Compensation Committee approved specific bonus targets for Dr. Steiner and the other executive officers, reflecting our corporate objectives for 2008, including achieving positive data from our ACAPODENE<sup>®</sup> clinical trials, successfully completing our Phase II clinical trial of Ostarine<sup>™</sup> for the treatment of cancer cachexia, progressing our SARMS into other clinical trials through our collaboration with Merck, moving certain preclinical compounds into human clinical trials, satisfactorily meeting our independent auditor's standards for a public company, and maintaining our expenses within the budget approved by our Board of Directors.

At its February 2008 meeting, the Compensation Committee also awarded Dr. Morton a discretionary bonus equal to \$28,000 to reward Dr. Morton for his efforts in undertaking specific roles and tasks since the beginning of 2008 that have proved instrumental in allowing us to achieve our goals for our clinical trial operations.

The Compensation Committee has continued to follow its conservative approach to issuing stock option awards to GTx's executive officers, granting annual stock options which are lower than peer average equity based awards for the same period. In 2007, the Compensation Committee approved stock option grants of 125,000 for Mr. Hanover and 25,000 each for our Vice Presidents, which grants were effective as of January 1, 2008. Consistent with past practices, no options

were issued to Dr. Steiner on account of the large number of shares of GTx common stock he currently holds. The Committee believed that a significant award of options to Mr. Hanover was warranted since it was the first option award Mr. Hanover has received from GTx and recognized the primary management role Mr. Hanover will serve in overseeing the potential commercialization of our product candidates.

Based on the Compensation Committee's review of the industry data compiled by Equilar and consistent with the Compensation Committee's intent to adjust executive compensation to a level consistent with the mean average compensation for our peer industry group, our Board of Directors approved, based upon the recommendation of the Compensation Committee, annual base salaries for 2008 for our named executive officers, as set forth in the table below. For the reasons stated above, salaries in excess of the median peer group salary targets were approved by the Committee for Dr. Morton and Mr. Hanover. Moreover, Mr. Hanover's 2008 salary increase largely reflects the Compensation Committee's belief that Mr. Hanover should be paid a base salary in excess of Dr. Morton.

Name	2008 Base Salary	Percentage Increase from 2007 Base Salary
Mitchell S. Steiner, M.D., F.A.C.S.	\$500,000	12%
Mark E. Mosteller	\$283,889	15%
Marc S. Hanover	\$435,000	42%
Ronald A. Morton, Jr., M.D., F.A.C.S	\$430,500	5%
Henry P. Doggrell	\$286,934	8%

#### Tax and Accounting Considerations

Section 162(m) of the Internal Revenue Code of 1986 limits our deduction for federal income tax purposes to not more than \$1 million of compensation paid to certain executive officers in a calendar year. Compensation above \$1 million may be deducted if it is "performance-based compensation." Our Compensation Committee has not yet established a policy for determining which forms of incentive compensation awarded to our executive officers should be designated to qualify as "performance-based compensation." To maintain flexibility in compensating our executive officers in a manner designed to promote our objectives, the Compensation Committee has not adopted a policy that requires all compensation to be deductible and in fact, none of the named executive officers received compensation in 2007 that would exceed the \$1 million limit on deductibility. However, the Compensation Committee intends to evaluate the effects of the compensation limits of Section 162(m) on any compensation it proposes to grant, and the Compensation Committee intends to provide future compensation in a manner consistent with our best interests and those of our stockholders. For example, we are currently requesting stockholders to approve a proposal that is intended maintain the tax deductible status of stock options that may be granted under our 2004 Equity Incentive Plan.

Effective January 1, 2006, we began accounting for share-based awards under the provisions of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, or FAS 123(R). FAS 123(R) establishes accounting for stock-based awards exchanged for employee services. Accordingly, stock-based compensation cost is measured at grant date, based on the fair value of the awards, and is recognized as an expense ratably over the requisite employee service period. The Compensation Committee has determined to retain for the foreseeable future our stock option program as the sole component of its long-term compensation program, and, therefore, to record this expense on an ongoing basis according to FAS 123(R). Accounting rules also require us to record cash compensation as an expense at the time the obligation is incurred.

#### Timing, grant date and exercise price for stock option awards

The Compensation Committee has consistently maintained a practice to award stock options only at specific times during the year. At a meeting scheduled late in the year, the Compensation Committee grants stock options to a broad group of employees, including executive officers, in amounts determined by the Compensation Committee. These grants are effective on January 1 of the following year with an exercise price equal to the closing price of GTx's common stock on the NASDAQ Global Market on the last trading day of the prior year. Other than the annual grants described above, the Compensation Committee will only consider additional grants for new employees, employees who are promoted or granted additional responsibilities or, more rarely, employees who have performed at a level that warrants recognition. These grants, if any, are made only on the date of a scheduled meeting of the Compensation Committee, in amounts determined



by the Compensation Committee, and with an exercise price equal to the closing price of GTx's common stock on the NASDAQ Global Market on the trading day immediately preceding the date of grant.

## **Conclusion**

The Compensation Committee believes the executive leadership of GTx is a key element to its success and that the compensation package offered to the executive officers is a key element in attracting and retaining the appropriate personnel.

The Compensation Committee believes it has historically maintained compensation for its executive officers at levels that are reflective of the talent and success of the individuals being compensated given our current stage of development, and, with the inclusion of additional compensation directly tied to performance, the Compensation Committee believes executive compensation will be sufficiently comparable to its industry peers to allow GTx to retain its key personnel at costs which are appropriate for GTx.

The Compensation Committee will continue to develop, analyze and review its methods for aligning executive management's long-term compensation with the benefits generated for stockholders. The Compensation Committee believes the idea of creating ownership in GTx helps align management's interests with the interests of stockholders. The Compensation Committee has no pre-determined timeline for implementing new or ongoing long-term incentive plans. New plans are reviewed, discussed and implemented as the Compensation Committee feels it is necessary and/or appropriate as a measure to incentivize, retain and/or reward GTx's executive officers.

## **COMPENSATION COMMITTEE REPORT<sup>(1)</sup>**

The Compensation Committee of the Board of Directors of GTx, Inc. has reviewed and discussed with management the information contained in the Compensation Discussion and Analysis section of this Proxy Statement and based on such review and discussion, has recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this Proxy Statement and incorporated into our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

### **COMPENSATION COMMITTEE:**

J. R. Hyde, III (Chairman)

Michael G. Carter

J. Kenneth Glass

Timothy R.G. Sear

<sup>(1)</sup> This Section is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filing of GTx under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

## EXECUTIVE COMPENSATION

### Summary Compensation Table

The following table sets forth certain summary information for the year indicated with respect to the compensation earned by our Chief Executive Officer, our Chief Financial Officer and each of the three other most highly compensated executive officers of GTx at December 31, 2007. We refer to these executive officers in this proxy statement as the "named executive officers."

#### SUMMARY COMPENSATION TABLE-FISCAL 2006 AND 2007

Name and Principal Position	Year	Salary (\$)	Bonus (\$)(1)	Option Awards (\$)(2)	Non-Equity Incentive Plan Compensation (\$)(3)	All Other Compensation (\$)(4)	Total (\$)
Mitchell S. Steiner, M.D., F.A.C.S. <i>Chief Executive Officer and Vice-Chairman of the Board of Directors</i>	2007	446,250	--	--	128,520	5,024	579,794
	2006	427,055	44,625	--	--	653	472,333
Mark E. Mosteller, CPA <i>Vice President, Chief Financial Officer and Treasurer</i>	2007	246,750	--	168,284(5)	66,623	9,226	490,883
	2006	236,692	12,338	129,499(6)	--	406	378,935
Marc S. Hanover <i>President and Chief Operating Officer</i>	2007	306,600	--	--	77,263	10,344	394,207
	2006	293,891	30,660	--	--	495	325,046
Ronald A. Morton, Jr., M.D., F.A.C.S. <i>Vice President, Chief Medical Officer</i>	2007	294,885(7)	--	111,676(8)	71,094	20,397	498,052
	2006	--	--	--	--	--	--
Henry P. Doggrell <i>Vice President, General Counsel and Secretary</i>	2007	265,650	--	117,357(9)	66,147	9,786	458,940
	2006	254,835	13,283	103,291(10)	--	423	371,832

- (1) On October 31, 2006, the Compensation Committee recommended, and the Board of Directors approved, a special one-time discretionary cash bonus to our named executive officers, other than Dr. Morton who joined us in April 2007. The Compensation Committee awarded the bonuses to recognize and reward the efforts of the named executive officers that resulted in the successful licensing of our product candidate, ACAPODENE®, to Ipsen Limited in Europe.
- (2) Represents the dollar amount recognized for financial statement reporting purposes with respect to the indicated fiscal year in accordance with Financial Accounting Standards Board Statement 123(R), or FAS 123(R). These amounts have been calculated in accordance with FAS 123(R) using the Black-Scholes-Merton option-pricing model. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeiture related to service-based vesting conditions. No stock options were forfeited by any of our named executive officers during fiscal 2006 or 2007. For a description of the assumptions made in determining the FAS 123(R) valuation, please refer to Note 3-Share-Based Compensation to our audited financial statements in our Annual Report on Form 10-K for the applicable fiscal year.
- (3) Represents amounts awarded to the named executive officers pursuant to our Executive Bonus Compensation Plan for fiscal 2007 performance. For more information on our Executive Bonus Compensation Plan, please see "Compensation Discussion and Analysis—What is our analysis of the compensation for our named executive officers in 2007?—Annual Bonus Awards" above as well as "Executive Compensation—Grants of Plan-Based Awards" below.
- (4) The amounts indicated represent: (a) the incremental cost of life insurance premiums to provide additional term life insurance benefits to the named executive officers equal to two times each executive's base salary, (b) supplemental long-term disability insurance for the named executive officers, (c) employer matching contributions to our defined contribution 401(K) Plan, and (d) in the case of Dr. Morton, the payment of \$12,355 in temporary living expenses in Memphis, Tennessee.
- (5) Represents the dollar amount recognized for financial statement reporting purposes with respect to the indicated fiscal year in accordance with FAS 123(R) for: (a) 17,000 options granted on April 11, 2002 (\$2,100); (b) 17,000 options granted on August 1, 2003 (\$27,901); (c) 25,500 options granted on September 1, 2003 (\$41,852); (d) 10,000 options granted on July 28, 2004 (\$10,598); (e) 25,000 options granted on July 27, 2005 (\$34,425); and (f) 25,000 options granted on January 1, 2007 (\$51,408).

- (6) Represents the dollar amount recognized for financial statement reporting purposes with respect to the indicated fiscal year in accordance with FAS 123(R) for: (a) 25,500 options granted on August 6, 2001 (\$7,134); (b) 17,000 options granted on April 11, 2002 (\$7,588); (c) 17,000 options granted on August 1, 2003 (\$27,901); (d) 25,500 options granted on September 1, 2003 (\$41,853); (e) 10,000 options granted on July 28, 2004 (\$10,598); and (f) 25,000 options granted on July 27, 2005 (\$34,425).
- (7) Represents a partial year of base salary from Dr. Morton's date of hire on April 12, 2007 through December 31, 2007.
- (8) Represents the dollar amount recognized for financial statement reporting purposes with respect to the indicated fiscal year in accordance with FAS 123(R) for 75,000 options granted on May 1, 2007 (\$111,676).
- (9) Represents the dollar amount recognized for financial statement reporting purposes with respect to the indicated fiscal year in accordance with FAS 123(R) for: (a) 12,750 options granted on September 1, 2003 (\$20,926); (b) 10,000 options granted on July 28, 2004 (\$10,598); (c) 25,000 options granted on July 27, 2005 (\$34,425); and (d) 25,000 options granted on January 1, 2007 (\$51,408).
- (10) Represents the dollar amount recognized for financial statement reporting purposes with respect to the indicated fiscal year in accordance with FAS 123(R) for: (a) 127,500 options granted on October 1, 2001 (\$37,342); (b) 12,750 options granted on September 1, 2003 (\$20,926); (c) 10,000 options granted on July 28, 2004 (\$10,598); and (d) 25,000 options granted on July 27, 2005 (\$34,425).

#### Grants of Plan-Based Awards

The following table summarizes grants of plan-based awards made to our named executive officers in 2007.

**GRANTS OF PLAN-BASED AWARDS TABLE—FISCAL 2007**

Name	Grant Date	Approval Date	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards(1)	All Other Option Awards: Number of Securities Underlying Options (#)(2)	Exercise or Base Price of Option Awards (\$/Sh)	Closing Market Price on Grant Date (\$/Sh)(3)	Grant Date Fair Value of Option Awards \$(4)
			Target (\$)				
Mitchell S. Steiner, M.D., F.A.C.S. <i>Chief Executive Officer and Vice-Chairman of the Board of Directors</i>	--	--	178,500	--	--	--	--
Mark E. Mosteller, CPA <i>Vice President, Chief Financial Officer and Treasurer</i>	1/1/2007	10/30/2006	74,025 --	25,000	17.84	17.84	257,888
Marc S. Hanover <i>President and Chief Operating Officer</i>	--	--	107,310	--	--	--	--
Ronald A. Morton, Jr., M.D., F.A.C.S. <i>Vice President, Chief Medical Officer</i>	5/1/2007	5/1/2007	88,868(5) --	75,000	19.51	19.75	836,198
Henry P. Doggrell <i>Vice President, General Counsel and Secretary</i>	1/1/2007	10/30/2006	79,695 --	25,000	17.84	17.84	257,888

- (1) This column sets forth the target amount of each named executive officer's annual cash bonus award for the year ended December 31, 2007 under our Executive Bonus Compensation Plan. The actual cash bonus award earned for the year ended December 31, 2007 under our Executive Bonus Compensation Plan for each named executive officer is set forth in the Summary Compensation Table above. As such, the amounts set forth in this column do not represent additional compensation earned by the named executive officers for the year ended December 31, 2007. For more information regarding our Executive Bonus Compensation Plan and the cash bonus awards granted to the named executive officers for the year ended December 31, 2007 thereunder, please see "Compensation Discussion and Analysis—What is our analysis of the compensation for our named executive officers in 2007?—Annual Bonus Awards" above.

- (2) The option vests in three equal annual installments beginning on the third anniversary of the grant date. For more information on the terms of the stock options granted to our named executive officers in fiscal 2007, please see "Executive Compensation—Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table—Option Awards" below.
- (3) Options are granted with an exercise price equal to 100% of the fair market value on the date of grant, which is determined by reference to the closing sales price of our common stock on the trading date immediately prior to the grant date. With respect to the options granted to Messrs. Mosteller and Doggrell, these options carry an exercise price of \$17.84 per share, the closing price of GTx's common stock on December 29, 2006, the last trading day immediately prior to the grant date. With respect to the option granted to Dr. Morton, this option carries an exercise price of \$19.51 per share, the closing price of GTx's common stock on April 30, 2007, the last trading day immediately prior to the grant date.
- (4) Represents the grant date fair value of each award determined in accordance with FAS 123(R).
- (5) Dr. Morton's target bonus under our Executive Bonus Compensation Plan was prorated to reflect his partial year of employment with GTx.

#### **Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table**

**Employment Agreements.** Each of our named executive officers has entered into a written employment agreement with GTx. Descriptions of our employment agreements with our named executive officers are included under the captions "Compensation Discussion and Analysis – What are the elements of our executive officer compensation program and why do we provide each element? – Employment Agreements" and "– Post-Employment Compensation" above, as well as "Executive Compensation – Potential Payments upon Termination or Change of Control" below.

**Annual Cash Bonus Awards.** Our Executive Bonus Compensation Plan provides for an annual cash bonus awards to reward executive officers for performance in the prior fiscal year. For more information regarding our Executive Bonus Compensation Plan, please see "Compensation Discussion and Analysis—What is our analysis of the compensation for our named executive officers in 2007?—Annual Bonus Awards" above.

**Option Awards.** Consistent with its practices for awarding stock options described in "Compensation Discussion and Analysis – Timing, grant date and exercise price for stock option awards," the Compensation Committee approved the grant of stock options to our named executive officers, except Dr. Steiner and Mr. Hanover, in the fall of 2006, which grants were effective on January 1, 2007. The exercise price for these stock options is \$17.84 per share, the closing price of GTx's common stock on December 29, 2006, the last trading day of 2006. The options vest in equal annual installments on January 1, 2010, 2011 and 2012. The options expire on January 1, 2017, unless they are forfeited or expire earlier in accordance with their terms. In connection with the commencement of Dr. Morton's employment with GTx, the Compensation Committee granted Dr. Morton an option to purchase 75,000 shares of GTx common stock on May 1, 2007. The exercise price for this stock option is \$19.51 per share, the closing price of GTx's common stock on April 30, 2007. The option vests in equal annual installments on May 1, 2010, 2011 and 2012. In addition, during the fall of 2007, the Compensation Committee approved the grant of a stock option to purchase 125,000 shares of GTx common stock to Mr. Hanover and options to purchase 25,000 shares of GTx common stock to each of the other named executive officers (except for Dr. Steiner), which grants were effective on January 1, 2008. The exercise price for these stock options is \$14.35 per share, the closing price of GTx's common stock on December 31, 2007, the last trading day of 2007. The options vest in equal annual installments on January 1, 2011, 2012 and 2013. Events that can accelerate the vesting of GTx's stock options are described below under "Executive Compensation—Potential Payments Upon Termination or Change of Control—Stock Option Vesting Acceleration."

**Other Compensatory Arrangements.** For a description of the other elements of our executive compensation program, see "Compensation Discussion and Analysis—What are the elements of our executive officer compensation program and why do we provide each element?"

## Outstanding Equity Awards at Fiscal-Year End

The following table summarizes the number of outstanding equity awards held by each of our named executive officers as of December 31, 2007.

### OUTSTANDING EQUITY AWARDS AT 2007 FISCAL-YEAR END TABLE

Name	Option Awards			
	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable		
Mitchell S. Steiner, M.D., F.A.C.S. <i>Chief Executive Officer and Vice-Chairman of the Board of Directors</i>	--	--	--	--
Mark E. Mosteller, CPA <i>Vice President, Chief Financial Officer and Treasurer</i>	23,000	--	6.78	08/06/11
	17,000	--	6.78	04/11/12
	11,334	5,666(1)	6.24	08/01/13
	17,000	8,500(2)	6.24	09/01/13
	3,334	6,666(3)	8.90	07/28/14
	--	25,000(4)	10.86	07/27/15
	--	25,000(5)	17.84	01/01/17
Marc S. Hanover <i>President and Chief Operating Officer</i>	--	--	--	--
Ronald A. Morton, Jr., M.D., F.A.C.S. <i>Vice President, Chief Medical Officer</i>	--	75,000(6)	19.51	05/01/17
Henry P. Doggrell <i>Vice President, General Counsel and Secretary</i>	112,500	--	6.78	10/01/11
	8,500	4,250(7)	6.24	09/01/13
	3,334	6,666(8)	8.90	07/28/14
	--	25,000(9)	10.86	07/27/15
	--	25,000(10)	17.84	01/01/17

(1) The remaining shares will vest on August 1, 2008.

(2) The remaining shares will vest on September 1, 2008.

(3) The remaining shares will vest as follows: 3,334 shares on July 28, 2008 and 3,333 shares on July 28, 2009.

(4) The shares vest in three equal annual installments beginning on July 27, 2008, the third anniversary of the grant date.

(5) The shares vest in three equal annual installments beginning on January 1, 2010, the third anniversary of the grant date.

(6) The shares vest in three equal annual installments beginning on May 1, 2010, the third anniversary of the grant date.

(7) The remaining shares vest on September 1, 2008.

(8) The remaining shares vest as follows: 3,334 shares on July 28, 2008 and 3,333 shares on July 28, 2009.

(9) The shares vest in three equal annual installments beginning on July 27, 2008, the third anniversary of the grant date.

(10) The shares vest in three equal annual installments beginning on January 1, 2010, the third anniversary of the grant date.

## Option Exercises and Stock Vested

The following table summarizes the number of options exercised and the value realized by our named executive officers as a result of such exercise during 2007. None of the named executive officers had any vesting of restricted stock awards during fiscal 2007.

### OPTION EXERCISES AND STOCK VESTED—FISCAL 2007

Name	Option Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise(\$)
Mitchell S. Steiner, M.D., F.A.C.S. <i>Chief Executive Officer and Vice-Chairman of the Board of Directors</i>	--	--
Mark E. Mosteller, CPA <i>Vice President, Chief Financial Officer and Treasurer</i>	--	--
Marc S. Hanover <i>President and Chief Operating Officer</i>	--	--
Ronald A. Morton, Jr., M.D., F.A.C.S. <i>Vice President, Chief Medical Officer</i>	--	--
Henry P. Doggrell <i>Vice President, General Counsel and Secretary</i>	10,000	79,900

## Potential Payments upon Termination or Change of Control

We have entered into employment agreements with each of our named executive officers. Described below are the circumstances that would trigger our obligation to make cash payments pursuant to these agreements following the termination of a named executive officer's employment and the cash payments that we would be required to provide. We also describe below the circumstances that would trigger the accelerated vesting of stock options held by our executive officers.

### Termination Without "Cause" or For "Good Reason" after a Change of Control

The employment agreements with our named executive officers contain cash post-termination change of control payments equal to one year's base salary. These change of control cash benefits that are structured on a "double-trigger" basis, meaning that before a named executive officer can receive a change of control payment: (1) a change of control must occur and (2) within six months of such change of control, the named executive officer's employment must be terminated for good reason or without cause. GTx's obligation to make the post-termination cash payments under the employment agreements is conditioned upon the former named executive officer's compliance with the provisions of the confidentiality and non-competition provisions, as applicable, of the employment agreement. The payment will be made over the 12 month-period following termination on our regular payroll dates rather than in a lump sum.

Generally, under our employment agreements with our named executive officers, a change of control is defined as:

- the sale of all or substantially all of GTx's assets;
- if any person acquires 50% or more of the GTx's voting securities (other than securities acquired directly from GTx in a public offering); or
- upon the consummation of a merger or consolidation of GTx with or into any other entity, if immediately after the transaction more than 50% of the voting stock of the surviving entity is held by persons who were not holders of at least 20% of GTx's voting stock prior to the transaction.

Each employment agreement defines "cause" as the named executive officer's:

- conviction for a felony;
- theft, embezzlement, misappropriation of or intentional infliction of material damage to GTx's property or business opportunities;
- breach of his confidentiality or non-competition provisions; or
- willful neglect of or failure to perform his duties or his ongoing willful failure or refusal to follow any reasonable, unambiguous duly adopted written direction of the Board that is not inconsistent with the description of such named executive officer's duties, after 30 days notice and the opportunity to cure.

Each employment agreement defines "good reason" as, following a change of control:

- a change in the named executive officer's status, position or responsibilities which represents a reduction in or demotion of the named executive officer's status, position or responsibilities in effect immediately prior to the change of control or the assignment to the named executive officer of duties or responsibilities that are inconsistent with such status, position or responsibilities;
- a reduction in salary in effect immediately prior to the change of control or a change in any benefit that materially and adversely affects the named executive officer;
- the relocation of the named executive officer's principal office to a location outside a thirty-mile radius of Memphis, Tennessee or where the named executive officer is permanently residing; or
- the failure of GTx to obtain an agreement reasonably satisfactory to the named executive officer from any successor or assignor of GTx to assume and agree to perform under the employment agreement.

#### *Other Termination Scenarios*

If we terminate a named executive officer's employment for "cause," or if a named executive officer voluntarily terminates his or her employment without "good reason," or upon the death of a named executive officer, the named executive officer would have no right to receive any compensation or benefits under the employment agreement on or after the effective date of termination, other than any accrued and unpaid salary. Likewise, if we terminate a named executive officer's employment without "cause," or if a named executive officer voluntarily terminates his employment with "good reason," in each case not in connection with a change of control, the named executive officer would have no right to receive any compensation or benefits under the employment agreement on or after the effective date of termination, other than any accrued and unpaid salary.

#### *Stock Option Vesting Acceleration*

Our 1999 Plan, 2000 Plan, 2001 Plan and 2002 Plan each provide that in the event of a specified change of control transactions, all shares subject to option awards under the plans will immediately vest and be converted into cash, options or stock of equivalent value in the surviving organization under terms and conditions that substantially preserve the economic status of plan participants. Certain of the options granted to our executive officers to date have been granted pursuant to these plans. Our 2004 Plan provides that in the event of specified corporate transactions such as a change of control or similar transaction, all outstanding options and stock appreciation rights under the 2004 Plan will be assumed, continued or substituted for by any surviving or acquiring entity. If the surviving or acquiring entity elects not to assume, continue or substitute for such awards, such equity awards held by individuals whose service has not terminated prior to the effective date of the corporate transaction will become fully vested, and, if applicable, exercisable and such equity awards will be terminated if not exercised prior to the effective date. Other forms of equity awards, such as restricted stock awards, may have their repurchase or forfeiture rights assigned to the surviving or acquiring entity. If such repurchase or forfeiture rights are not assigned, then such equity awards will become fully vested prior to the effective date of the transaction. Following specified change of control transactions, the vesting and exercise of equity awards generally will be accelerated only if the recipient's award agreement so specifies. The standard form of stock option agreement under the 2004 Plan

provides for each stock option to become fully vested and exercisable if the option holder's service with GTx or its successor terminates within twelve months after a change of control and the termination of service is a result of an involuntary termination without cause or a constructive termination.

#### Calculation of Benefits

The following table includes an estimate of the potential compensation and benefits payable to our named executive officers in certain termination and change of control situations. In providing the estimated potential payments and benefits, we have made the following general assumptions in all circumstances where applicable:

- a change of control event has occurred and the date of termination is December 31, 2007;
- the closing price of our common stock on that date is \$14.35;
- the annual salary at the time of termination is as follows: Mitchell S. Steiner, \$446,250; Mark E. Mosteller, \$246,750; Marc S. Hanover \$306,600; Ronald A. Morton, Jr., \$410,000; and Henry P. Doggrell, \$265,650;
- all then-unvested stock options became fully vested as a result of the change of control and the value of stock options that vest is equal to the difference between the closing price of our common stock of \$14.35 on December 31, 2007 and the exercise price times the number of options that vest;
- there is no unpaid bonus for the prior year;
- there is no accrued and unpaid salary; and
- there is no unpaid reimbursement for expenses incurred prior to the date of termination.

Name	Salary Continuation	Stock Option Vesting Acceleration
	Termination w/o Cause or for Good Reason in Connection with Change in Control (\$)	Change in Control (\$)
Mitchell S. Steiner, M.D., F.A.C.S. <i>Chief Executive Officer and Vice-Chairman of the Board of Directors</i>	446,250	--(1)
Mark E. Mosteller, CPA <i>Vice President, Chief Financial Officer and Treasurer</i>	246,750	238,466(2)
Marc S. Hanover <i>President and Chief Operating Officer</i>	306,600	--(3)
Ronald A. Morton, Jr., M.D., F.A.C.S. <i>Vice President, Chief Medical Officer</i>	410,000	--(4)
Henry P. Doggrell <i>Vice President, General Counsel and Secretary</i>	265,650	158,048(5)

- (1) As of December 31, 2007, Dr. Steiner did not hold any options for GTx common stock or any restricted stock that would vest upon any termination event.
- (2) Represents the amount potentially realizable by Mr. Mosteller resulting from the immediate vesting of previously unvested options as indicated in the following table:

Number of Securities Underlying Unvested Options	Exercise Price(\$)	Closing Price on December 31, 2007	Amount Potentially Realizable(\$)
14,166	6.24	14.35	114,886
6,666	8.90	14.35	36,330
25,000	10.86	14.35	87,250
25,000	17.84	14.35	--



- (3) As of December 31, 2007, Mr. Hanover did not hold any options for GTx common stock or any restricted stock that would vest upon any termination event.
- (4) All of Dr. Morton's unvested option shares were out-of-the-money based on the closing price of GTx common stock on December 31, 2007.
- (5) Represents the amount potentially realizable by Mr. Doggrell resulting from the immediate vesting of previously unvested options as indicated in the following table:

Number of Securities Underlying Unvested Options	Exercise Price(\$)	Closing Price on December 31, 2007	Amount Potentially Realizable(\$)
4,250	6.24	14.35	34,468
6,666	8.90	14.35	36,330
25,000	10.86	14.35	87,250
25,000	17.84	14.35	--

### DIRECTOR COMPENSATION

*Retainer and Fees.* We pay our non-employee directors retainers in quarterly increments based on an annualized rate of \$20,000 a year, or \$30,000 a year for our Audit Committee Chair. In addition, effective July 2007, we started paying our non-employee directors \$1,500 for every regularly scheduled (or special) meeting of the Board and its committees attended, and \$750 per telephonic meeting, payable quarterly in arrears. No directors currently receive consulting fees from GTx. Directors who are also our employees (currently Dr. Steiner and Mr. Hanover) receive no additional compensation for service on the Board.

*Directors' Deferred Compensation Plan.* Since June 30, 2004, our non-employee directors have had the opportunity to defer all or a portion of their fees under our Directors' Deferred Compensation Plan. Deferrals can be made into a cash account, a stock unit account, or a combination of both. Deferrals into a cash account accrue interest at the prime rate of interest announced from time to time by a local bank utilized by us, and deferrals into a stock account accrue to the deferring director rights in shares of GTx common stock equal to the cash compensation then payable to the director for his or her Board service divided by the then current fair market value of GTx common stock. Currently, all but two non-employee directors have elected to defer their Board compensation into stock unit accounts, although all but one director deferred their Board compensation under the Directors' Deferred Compensation Plan through December 31, 2007. No directors have deferred their Board compensation into cash accounts. Under the Directors' Deferred Compensation Plan, a director may elect to receive a distribution of amounts credited to such cash or stock unit accounts on a date selected by the director at the time of the election. However, if the director retires or separates from the Board prior to his or her selected distribution date, the amount credited to the director's cash account under the Directors' Deferred Compensation Plan will be distributed within 30 days after commencement of the year following such retirement or separation, and the amount credited to the director's stock account will be distributed within the later of (a) 30 days after commencement of the year following such retirement or separation, or (b) six months after such event. All distributions under our Directors' Deferred Compensation Plan will be made in the form of a single lump sum in cash (for amounts credited to cash accounts) or in shares of GTx common stock (for amounts credited to stock unit accounts), except that any fractional shares of GTx common stock will be distributed in cash valued at the then current fair market value of GTx common stock.

*Stock Options.* Our Directors' Option Plan provides for the automatic grant of initial and annual nonstatutory stock options to GTx's non-employee directors who do not own more than ten percent of the combined voting power of GTx's then outstanding securities. The exercise price per share for the options granted under the plan is not less than the fair market value of the stock on the date of grant. Pursuant to the Directors' Option Plan, any individual who first becomes a non-employee director automatically is granted an option to purchase shares of common stock. The number of shares subject to each of these initial grants is currently 10,000 shares, provided that the number of shares may be increased or decreased by our Board of Directors in its sole discretion. Any individual who is serving as a non-employee director on the day following an annual meeting of GTx's stockholders automatically will be granted an option to purchase shares of common stock on that date; provided, however, that if the individual has not been serving as a non-employee director for the entire period since the preceding annual meeting, the number of shares subject to such individual's annual grant will be

reduced pro rata for each full month prior to the date of grant during which such individual did not serve as a non-employee director. The number of shares subject to each annual grant is currently 8,000 shares, provided that the number of shares may be increased or decreased by our Board of Directors in its sole discretion. The shares subject to each initial grant and each annual grant vest in a series of three successive equal annual installments measured from the date of grant, so that each initial grant and each annual grant will be fully vested three years after the date of grant. In the event of specified corporate transactions, as defined in the Directors' Option Plan, all outstanding options under the Directors' Option Plan may be assumed or substituted for by any surviving or acquiring entity. If the surviving or acquiring entity elects not to assume or substitute for such options, then (a) with respect to any such options that are held by optionees then performing services for GTx or its affiliates, the vesting and exercise of such options will be accelerated in full and such options will be terminated if not exercised prior to the effective date of the corporate transaction, and (b) all other outstanding options will terminate if not exercised prior to the effective date of the corporate transaction. If a specified change of control transaction occurs, as defined in the Directors' Option Plan, then the vesting and exercise of the optionee's options will be accelerated in full immediately prior to (and contingent upon) the effectiveness of the transaction. If an optionee is required to resign his or her position as a non-employee director as a condition of the transaction, the vesting and exercise of the optionee's options will be accelerated in full immediately prior to the effectiveness of such resignation.

The table below represents the compensation earned by each non-employee director during 2007.

#### DIRECTOR COMPENSATION—FISCAL 2007

Name	Fees Earned or Paid in Cash \$(1)	Option Awards \$(2)	Total (\$)
J. R. Hyde, III	24,500	--	24,500
John H. Pontius	24,500	44,088	68,588
Rosemary Mazanet, M.D., Ph.D.	24,500	44,088	68,588
J. Kenneth Glass	25,250	44,950	70,200
Andrew M. Clarkson	34,500	44,950	79,450
Timothy R. G. Sear	25,250	55,340	80,590
Robert W. Karr, M.D.	24,500	53,185	77,685
Michael G. Carter, M.D.	23,750	41,086	64,836

- (1) Represents fees earned in 2007. Each director in the table above, other than Dr. Carter, elected to defer his or her fees pursuant to the Directors' Deferred Compensation Plan.
- (2) This column represents the dollar amount recognized for financial statement reporting purposes with respect to the year ended December 31, 2007 in accordance with FAS 123(R). These amounts have been calculated in accordance with FAS 123(R) using the Black-Scholes-Merton option-pricing model. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeiture related to service-based vesting conditions. No stock options were forfeited by any of our non-employee directors during fiscal 2007. For a description of the assumptions made in determining the FAS 123(R) valuation, please refer to Note 3 – Share-Based Compensation to our audited financial statements in our Annual Report on Form 10-K for the year ended December 31, 2007.

The following table indicates the grant date fair value for each stock option awarded to our non-employee directors during the year ended December 31, 2007, as determined in accordance with FAS 123(R), as well as the total number of shares subject to options outstanding as of December 31, 2007 for each non-employee director:

Name	FAS 123(R) Grant Date Fair Value (\$)	Total Shares Subject to Options Outstanding at 12/31/2007 (#)
John H. Pontius	85,168	28,000
Rosemary Mazanet, M.D., Ph.D.	85,168	28,000
J. Kenneth Glass	85,168	28,000
Andrew M. Clarkson	85,168	28,000
Timothy R. G. Sear	85,168	16,666
Robert W. Karr, M.D.	85,168	25,334
Michael G. Carter, M.D.	81,623	17,667

## COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

During the year ended December 31, 2007, the Compensation Committee consisted of Mr. Hyde, as Chairman, Dr. Carter, Mr. Glass and Mr. Sear. None of the current members of the Compensation Committee is or was an officer or employee of GTx. During 2007, none of GTx's executive officers served as a director or member of the compensation committee of any other entity whose executive officers served on the GTx's Board of Directors or Compensation Committee.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

### Policies and Procedures for Review of Related Party Transactions

Upon recommendation of the Audit Committee, the Board adopted a related party transactions policy, which specifies GTx's policies and procedures regarding transactions between GTx and its employees, officers, directors or their family members. GTx's General Counsel is responsible for (a) ensuring that policy is distributed to all GTx officers, directors and other managers and (b) requiring that any proposed related party transaction be presented to the Audit Committee for consideration before GTx enters into any such transactions. This policy can be found on GTx's website ([www.gtxinc.com](http://www.gtxinc.com)) under "About GTx" at "Corporate Governance."

It is the policy of GTx to prohibit all related party transactions unless the Audit Committee determines in advance of GTx entering into any such transaction that there is a compelling business reason to enter into such a transaction. There is a general presumption that the Audit Committee will not approve a related party transaction with GTx. However, the Audit Committee may approve a related party transaction if:

- The Audit Committee finds that there is a compelling business reason to approve the transaction, taking into account such factors as the absence of other unrelated parties to perform similar work for a similar price within a similar timeframe; and
- The Audit Committee finds that it has been fully apprised of all significant conflicts that may exist or otherwise arise on account of the transaction, and it believes, nonetheless, that GTx is warranted entering into the related party transaction and has developed an appropriate plan to manage the potential conflicts of interest.

### Certain Transactions With or Involving Related Persons

*Licensed SARM Technology.* James T. Dalton, Ph.D., GTx's Vice President, Preclinical Research & Development, is a party to an agreement among the University of Tennessee, or UT, the University of Tennessee Research Foundation, or UTRF, and the inventors of many of the patents filed by UT and UTRF for selective androgen receptor modulator, or SARM, technology, which was entered while Dr. Dalton and the other inventors were employed by UT. Under this agreement, all rights in the SARM technology were assigned to UTRF with the commitment that payments received by UTRF from the licensing of the SARM technology would be shared between UT and the inventors, including Dr. Dalton. In 2002, subsequent to Dr. Dalton entering into this agreement, the SARM technology was licensed exclusively to GTx. In 2005, Dr. Dalton became one of GTx's employees. In July 2007, GTx and UTRF entered into a Consolidated, Amended, and Restated License Agreement to consolidate and replace GTx's previously existing SARM license agreements with UTRF and to modify and expand certain rights and obligations of each of the parties. GTx agreed to pay to UTRF a one-time, upfront fee of \$290,000 as consideration for entering into the new SARM agreement. GTx also agreed to pay an annual license maintenance fee during the term of the new SARM agreement, which fee is creditable against various royalties GTx agreed to pay to UTRF on sublicense revenues and net sales of products subject to the new SARM agreement. Since joining GTx in 2005, Dr. Dalton received from UT and UTRF a portion of the payments made by GTx to UTRF for the licensing of the SARM technology totaling approximately \$454,644. Dr. Dalton will continue to receive a portion of the payments GTx will make to UTRF under the SARM agreement in accordance with the agreement among the UT scientists, including Dr. Dalton, UT and UTRF. Since Dr. Dalton's interest in GTx's agreement with UTRF arose while Dr. Dalton was an employee of UTRF, not GTx, and GTx's initial arrangements with UTRF regarding the licensing of the SARM technology were created in 2002, our related party transactions policy did not require that the Audit Committee review and approve the transaction in advance. The members of the Audit Committee were, however, aware of

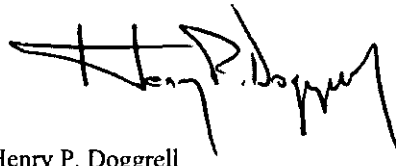
Dr. Dalton's interest when the GTx Board of Directors approved the entering into of the new SARM agreement with UTRF in July 2007, and so informed the other members of the Board.

*Indemnity Agreements.* GTx has entered into indemnity agreements with each of its current directors and certain of its executive officers to give such directors and officers additional contractual assurances regarding the scope of the indemnification set forth in GTx's charter and bylaws and to provide additional procedural protections.

#### OTHER MATTERS

The Board of Directors, at the time of the preparation of this proxy statement, knows of no business to come before the meeting other than that referred to herein. If any other business should properly come before the meeting, the person named in the enclosed proxy will have discretionary authority to vote all proxies in accordance with his best judgment.

By Order of the Board of Directors,

A handwritten signature in black ink, appearing to read "Henry P. Doggrell", written over a horizontal line.

Henry P. Doggrell  
*Vice President, General Counsel and  
Secretary*

Memphis, Tennessee  
March 12, 2008

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## PRODUCT CANDIDATE PIPELINE

PROGRAM/INDICATION	CLASS	PRECLINICAL	PHASE I	PHASE II	PHASE III	MARKETED
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<b>FARESTON®</b>						
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*For the treatment of advanced breast cancer*

<b>ACAPODENE®</b>						
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*For the treatment of multiple serious side effects of androgen deprivation therapy*

<b>ACAPODENE®</b>						
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*For the prevention of prostate cancer in high risk men with high grade PIN*

<b>OSTARINE™</b>						
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*For the treatment of cancer cachexia*

<b>OSTARINE™</b>						
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*For the treatment of sarcopenia*

<b>GTx-838</b>						
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*For the treatment of sarcopenia*

<b>GTx-758</b>						
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*For the treatment of advanced prostate cancer*

<b>GTx-878</b>	<b>ERβ AGONIST</b>					
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*For the treatment of BPH, chronic prostatitis*





*"We have achieved much in our first ten years. Looking ahead, we will remain science driven and focused on the discovery, development, and now also the commercialization of novel small molecules targeting hormone pathways to address unmet medical needs in men and women."*

Mitchell S. Steiner, MD, FACS  
GTx Vice Chairman, CEO



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## Transforming

### TRANSFORMING FROM R&D TO THE REALITY OF HOPE IN HEALTH WITH NOVEL, TARGETED SOLUTIONS FOR UNMET MEDICAL NEEDS

*Entering its second decade, GTx is transforming from a company based on the discovery and development of drug candidates into one that will also commercialize our products. Our successful in-house discoveries have allowed GTx to broaden its mission beyond our original focus on men's health. GTx is a company with recognized scientific expertise in the discovery and development of novel small molecules that selectively target hormone pathways—yielding therapeutics with the potential to address unmet medical needs in men and women.*

Our lead product is Acapodene® (toremifene citrate), a selective estrogen receptor modulator (SERM), designed to maximize the beneficial clinical effects of estrogen while minimizing its unwanted side effects. We are developing Acapodene 80 mg to treat multiple side effects of androgen deprivation therapy (ADT) for advanced prostate cancer and Acapodene 20 mg to prevent prostate cancer in high risk men with a precancerous lesion, high grade prostatic intraepithelial neoplasia (PIN).

In early 2008, we announced that in the Phase III ADT clinical trial, Acapodene 80 mg as a daily oral dose reduced vertebral fractures, the primary endpoint of the trial, and also increased bone mineral density, reduced hot flashes, ameliorated gynecomastia, and improved lipid profiles. GTx plans to file a New Drug Application (NDA) for marketing approval with the U.S. Food and Drug Administration by summer 2008. GTx plans to conduct an efficacy interim analysis of the Acapodene 20 mg Phase III high grade

PIN clinical trial in late first quarter. With positive results, GTx may file a second NDA in 2008.

GTx entered into a global strategic collaboration with Merck & Co., Inc. for the discovery, development and commercialization of selective androgen receptor modulators (SARMs). GTx and Merck are pooling SARM candidates and research programs in this unique collaboration which validates our R&D and will expedite the development and commercialization of first-in-class SARM drugs.

GTx's SARM program started in the 1990s when scientists Jim Dalton, PhD, and Duane Miller, PhD, were conducting research on androgen receptor *antagonist* molecules in search of new prostate cancer treatments. Instead they discovered selective *agonists*. GTx CEO Mitchell Steiner, MD, recognized the potential of these molecules to build muscle and bone and encouraged them to push forward. In 2006, GTx solidified its leadership in SARM development, when its lead SARM, Ostarine™, demonstrated in a Phase II clinical trial the ability to build muscle and improve physical performance in elderly men and postmenopausal women.

With the most advanced SARM programs, GTx and Merck are the best partners to lead the development of this new class of drugs to treat a variety of muscle wasting and bone loss indications, including frailty or sarcopenia, cancer cachexia, and other musculoskeletal wasting conditions.

*"GTx has established a strong scientific reputation in the research and development of novel SARMs that offer a promising alternative to androgen therapy. We look forward to working with Dr. Steiner and his team."*

Alan B. Ezekowitz, MBChB, D.Phil.  
Senior Vice President, Merck Research Laboratories

## Affirming

### **STRONG SCIENCE AFFIRMS THE VISION ... RESEARCH AND RESULTS AFFIRM THE SCIENCE**

*GTx's scientific and clinical vision has led us to identify opportunities ahead of the competition.*

GTx pioneered the use of a selective estrogen receptor modulator (SERM) in men. SERMs are small molecules which bind to estrogen receptors but display different clinical activities—acting as estrogens or antiestrogens—depending on tissue type. Estrogen plays a critical role in men's health, promoting bone strength, maintaining cholesterol levels, and regulating certain pituitary and central nervous system functions. In some tissues, however, such as the prostate, a shift in the balance between estrogens and testosterone may promote benign prostatic hyperplasia (BPH) and cancer.

Androgen deprivation therapy (ADT) is effective treatment for advanced prostate cancer. ADT lowers testosterone and estrogen, forcing the cancer into remission. Low estrogen levels result in multiple serious side effects. GTx recognized that the selective estrogen activity of Acapodene, a SERM, may complement ADT by restoring the needed estrogen effects on bone, brain, and lipids, while still blocking its harmful effects on prostate and breast. The success of the Acapodene 80 mg Phase III ADT clinical trial confirms a SERM can address these estrogen related side effects.

Estrogen is a promoter of prostate cancer. GTx recognized that Acapodene 20 mg, which selectively blocks estrogen in the prostate, might prevent prostate cancer. Before many other pharmaceutical companies began

targeting precancerous lesions to reduce cancer risk, GTx focused clinical development efforts on men diagnosed with high grade PIN, the precancerous lesion of the prostate, who have the highest risk for prostate cancer.

While others searched with little success for non-steroidal small molecules able to bind to and selectively modulate the androgen receptor, GTx pushed forward and developed the leading selective androgen receptor modulator (SARM) program. Our Phase II clinical trial of Ostarine in 120 elderly men and post-menopausal women demonstrated that a SARM can build muscle without certain unwanted side effects such as stimulating prostate in men or hair growth in women. SARMs are now a major focus of pharmaceutical research.

#### **CHOOSING THE BEST PARTNERS**

GTx has established strategic collaborations which serve to deepen and strengthen our R&D and expedite commercialization of our product candidates.

GTx selected Ipsen Group as the partner to commercialize Acapodene in Europe. Ipsen's leading product is Decapeptyl®, an ADT drug. Ipsen has the clinical, regulatory and commercial capabilities to bring Acapodene to European patients.

Our alliance with Merck affirms muscle wasting diseases as an important frontier in drug development and commercialization. We believe that Merck has the world class scientific, clinical and commercial expertise to capture the potential of SARMs.

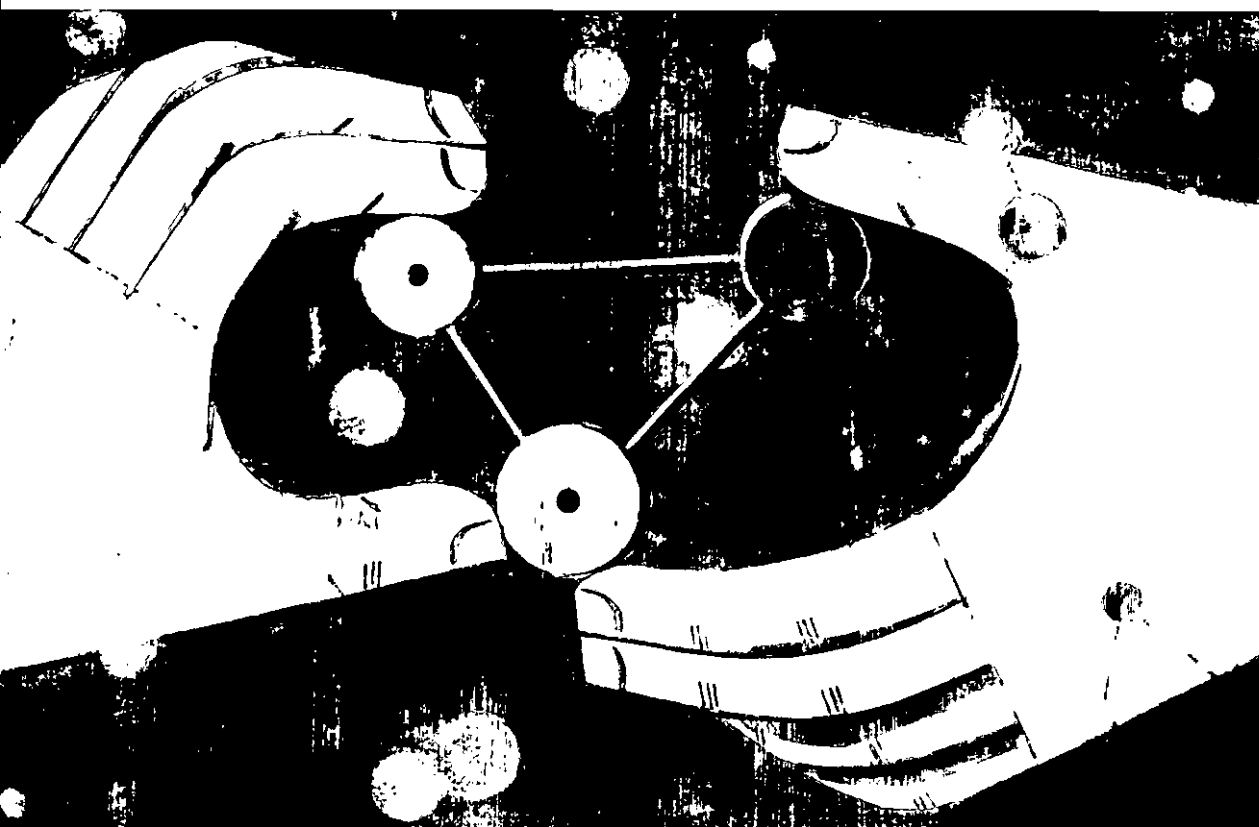
Engaging the right partners is an important means for extending, deepening and strengthening our capabilities.



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*With the successful development of Acapodene and the GTx SARM program, we have established a strong scientific reputation as a company with an expertise in the discovery and development of novel selective hormonal therapeutics.*



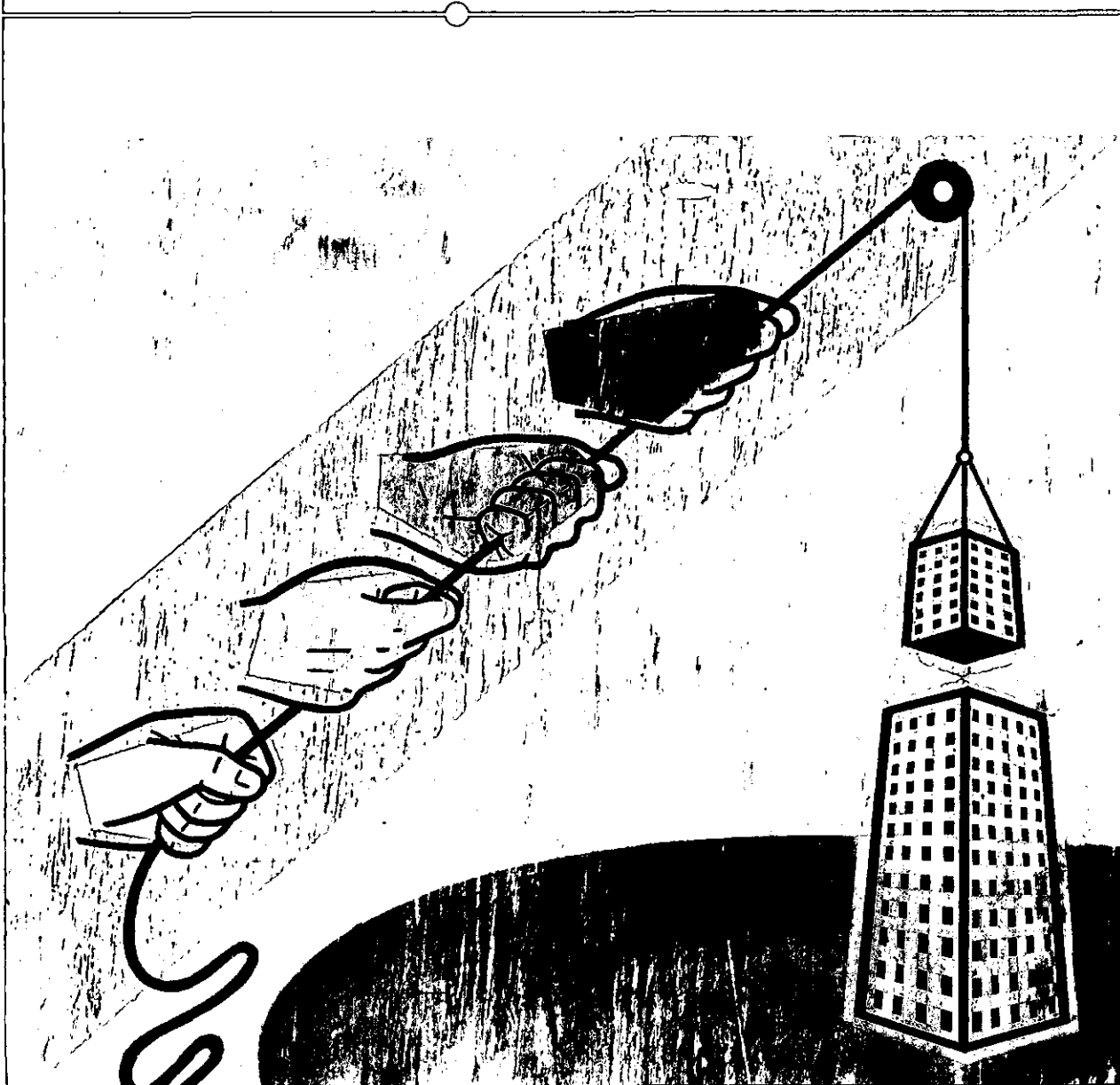


*"GTx has positioned itself well  
to commercialize multiple  
product opportunities that  
address unmet medical needs."*

**Christopher K. West**  
GTx Vice President, Sales

*The strong scientific foundation  
of GTx has allowed us to build  
relationships that strengthen  
our business capabilities  
and give us the power  
of global commercialization.*

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*"At GTx, I have the opportunity to make a greater impact on the prostate cancer community than if I were taking care of individual patients. This team has a pioneering and revolutionary spirit, and the research in hormone receptors is based on quality science. It's an exciting time, and we're only at the beginning of what can be done here."*

Ronald A. Morton Jr., MD, FACS  
GTx Vice President, Chief Medical Officer



## Building

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### BUILDING TEAMS TO ENSURE OUR OBJECTIVES ARE MET

*In 2007, we took steps to build GTx to take advantage of the scientific and commercial opportunities we see developing over the next ten years. GTx has established a strong scientific reputation with the successful development of Acapodene and our SARM program, and we continue to recruit top talent to GTx. Last year 25 new employees joined our company, many in preclinical development. Our team now includes 7 MDs and 24 PhDs, with a total of nearly 120 full-time employees.*

#### STRONG NEW TEAM MEMBERS IN 2007

Ronald A. Morton Jr., MD, FACS, was appointed Vice President and Chief Medical Officer in 2007. With a background in urology, Dr. Morton shares GTx's enthusiasm for the science behind nuclear hormone receptors. "GTx has a unique structure and leadership team," says Dr. Morton. "Both Dr. Steiner and I are former urology department chairmen. With quality research, talent at all levels, and a rich, stimulating intellectual environment, GTx is ready to meet hard challenges now and far into the future." As we execute our commercialization plans for Acapodene, Dr. Morton strengthens our management team with his clinical insights and provides outstanding medical leadership with his esteemed reputation and global network in the urology community.

Jeff Hesselberg was appointed Vice President, Regulatory Affairs. His 19 years of experience in the biopharmaceutical industry, including 13 years in regulatory affairs, brings essential leadership to GTx as we prepare to file New Drug Applications (NDA) for Acapodene and as GTx and Merck advance Ostarine and other SARMs through clinical development. "It was the chance to work with a company that has a great management team and many opportunities—so many shots on goal—that drew me to GTx," says Mr. Hesselberg. "I believe this company has the potential to provide patients with meaningful therapeutic options."

Chris West joined GTx as Vice President, Sales. He has more than 14 years of pharmaceutical sales and marketing experience that will prove invaluable to GTx as we commercialize our product candidates. "I was drawn to GTx because it's a science-driven company with strong business management that is being built for the future," says Mr. West. "We not only talk about products for 2008 and 2009, but also we talk about what's going to be happening in 2012 or 2013. The GTx innovations in SERMs and SARMs promise to give people a chance to combat chronic disease and live longer with a better quality of life. I'm proud to be part of such an incredibly dynamic team."



*"The depth of the GTx pipeline was a real draw for me. I know that GTx has a long, sustainable future and I wanted to be part of that."*

**Jeffrey G. Hesselberg**

*GTx Vice President, Regulatory Affairs*

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## Sustaining

### A DEEP PIPELINE, A COMMERCIAL STRATEGY AND PROVEN SCIENCE SUSTAIN OUR FUTURE

*As we enter our second decade, we stand prepared for the commercialization of Acapodene, and we are excited by the opportunities of SARMS and other product candidates in our expanding pipeline.*

#### COMMERCIAL STRATEGY IN PLACE

In February 2008, GTx announced the successful results of the Acapodene 80 mg Phase III ADT clinical trial. We intend to file a NDA this year to seek marketing approval for Acapodene 80 mg, and we may have the opportunity to file a second NDA later this year if Acapodene 20 mg is successful in the planned efficacy interim analysis of the Phase III high grade PIN clinical trial. With the potential for a 2009 launch of Acapodene, assuming a successful FDA review and approval, we are expanding our commercial team and operations to ensure that these new products are made available to patients.

Our strategy is to commercialize Acapodene in the U.S. and North America. The opportunities for both Acapodene 80 mg and Acapodene 20 mg are attractive. Approximately 800,000 prostate cancer patients in the U.S. are on ADT, and 100,000 new patients initiate therapy annually. Each year high grade PIN is detected by needle biopsy in at least 115,000 men following a finding of elevated PSA.

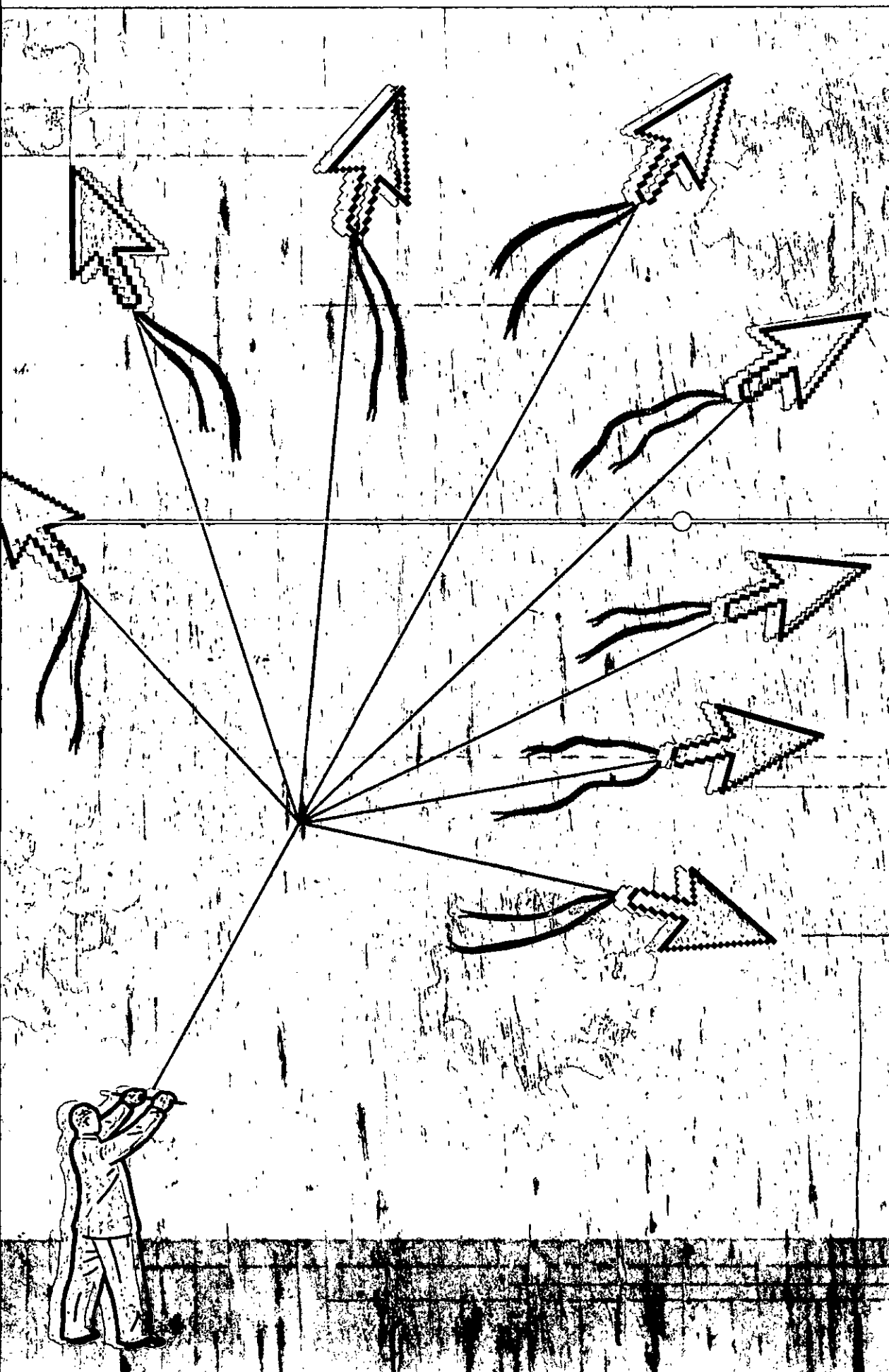
Beyond the U.S., we have licensed European distribution rights for Acapodene to Ipsen Group, and we plan to partner Acapodene in the rest of the world.

#### SUSTAINING GROWTH THROUGH THE GTx PIPELINE

GTx and Merck are working to capture the full opportunity of the SARM class. Together we intend to develop multiple product candidates for indications across a wide spectrum of therapeutic areas, including frailty or sarcopenia, cancer cachexia, and potentially other muscle wasting diseases.

GTx has selected two new candidates for clinical development from our drug discovery pipeline: GTx-758 and GTx-878. GTx-758, an oral LH inhibitor, is a new approach to androgen deprivation therapy for advanced prostate cancer. In preclinical models, GTx-758 has demonstrated the ability to lower testosterone without many of the serious side effects common to current forms of ADT, such as Lupron® and Zoladex®. GTx-878, an ERβ agonist, shows promise as a novel treatment for BPH. In preclinical models, GTx-878 has demonstrated the ability to inhibit prostate growth, relax smooth muscle and decrease inflammation. We have composition of matter and method of use patents for both drug candidates. We plan to initiate clinical testing of GTx-758 and GTx-878 in 2008 and 2009, respectively.

With our expertise in selective hormonal therapeutics, an expanding portfolio of product candidates, a growing and talented team, and partners who share our vision, we are building a company that is focused on bringing important new therapies to patients and is positioned for growth.







Mitchell S. Steiner, MD, FACS  
Vice Chairman and  
Chief Executive Officer

## To Our Shareholders

*GTx passed a milestone in 2007, our 10th anniversary.*

In September 1997, Marc Hanover and I co-founded GTx with the vision to bring new treatments to prostate cancer patients. Our initial idea for GTx was the development of gene therapy products for cancer—hence, our original name, Genotherapeutics. We concluded early on that gene therapy held promise perhaps in the very distant future. We consequently shifted our focus back to near term opportunities and what has become our core competency—developing small molecules which selectively modulate hormone pathways in clinically beneficial ways—and shortened our name to GTx, Inc.

J. R. “Pitt” Hyde III, our chairman, joined us at the start of 1998. Pitt was GTx’s lead financier, and he brought to GTx a focus on corporate culture and long-term value creation, traits instilled in him through his experiences founding and building AutoZone and serving on the boards of Wal-Mart and FedEx.

Over the last decade, we have learned many lessons about what is required to build a successful drug development company. Biotech business plans must be flexible and adaptable. Pharmaceutical research requires scientific ingenuity to identify products early in the development process which hold the promise of clinical and commercial relevance. Bringing new medicines to market is a complex business, so engaging the right partners on equitable terms is an important means for extending, deepening and strengthening our capabilities. Finally, we have been extremely fortunate to have assembled a talented and dedicated team of scientists, clinicians and business leaders.

*Flexibility, ingenuity, productivity and efficiency*

Soon after incorporating GTx, we brought forward Acapodene® (toremifene citrate) as a potential medicine for prostate cancer prevention. We also recognized that as a selective estrogen receptor modulator, or SERM, Acapodene held promise as a potential treatment for the estrogen related side effects of ADT—bone loss, adverse lipid changes, hot flashes, and gynecomastia. By the time we became a public company in February 2004, we were evaluating Acapodene in two separate doses for two distinct indications in men: at a 20 mg dose for the prevention of prostate cancer in high risk men with high grade prostatic intra-epithelial neoplasia, or PIN, and at an 80 mg dose for the treatment of multiple serious side effects of androgen deprivation therapy for prostate cancer. With the focus on prostate cancer related indications, we were known as “the men’s health biotech company.”

During the same period, our team was advancing our discovery and development program for selective androgen receptor modulators, or SARMs. These novel small molecules which bind to and stimulate or block the androgen receptor in a tissue selective manner were designed to confer the benefits of testosterone without certain unwanted clinical side effects, such as stimulation of the prostate or hair growth in women. SARMs, which were first described in the scientific literature by GTx scientists, are a new frontier in pharmaceutical research. Now with our partner, Merck & Co., Inc., we are developing SARMs to address frailty or sarcopenia, cancer cachexia and other musculoskeletal loss conditions.

With the success of our SARMs, which have broad therapeutic potential in both men and women, we reexamined our corporate identity. With Acapodene, a SERM, and with our SARMs, GTx has demonstrated that it has deep expertise in the discovery and development of novel small molecules that selectively target hormone pathways. GTx has become a company that develops and uses a variety of novel selective nuclear hormone receptor modulators to address a myriad of unmet medical needs in men and women.

This expertise continues to produce promising new molecules for clinical development. By year end 2008, we are planning to initiate clinical testing of GTx-758, an oral LH inhibitor

which is an exciting new approach to ADT. In preclinical models, GTx-758 demonstrated the potential to induce androgen deprivation without, we believe, many of the life threatening side effects common to LHRH agonists. The second product candidate, GTx-878, is an estrogen receptor beta agonist for benign prostatic hyperplasia, or BPH. Current BPH drugs either reduce prostate size or relax prostate smooth muscle tone. In preclinical models, GTx-878 has demonstrated three activities that may be beneficial to treat BPH: the potential to inhibit prostate growth, relax smooth muscle tone and reduce inflammation. GTx is planning to initiate Phase I clinical testing in the first half of 2009.

At GTx, we strive to be good stewards of your resources. To date, we have raised approximately \$257 million in equity. With this capital, we have built a company with a well defined scientific expertise and a product candidate portfolio rich with opportunities. We have two Phase III assets, one of which has successfully completed clinical testing to allow us to file a NDA for marketing approval, the leading SARM program moving forward rapidly with Merck as our collaboration partner, and two attractive new molecules from the GTx preclinical pipeline progressing into clinical development for potentially large indications. All this, and in January 2008, we still had approximately \$145 million in cash, cash equivalents, and short term investments.

#### *An independent scientific vision*

Pursuing drug development for unmet medical needs requires independence of thought and the conviction to maintain even controversial positions if you believe your approach to be correct. Hard work and good science are usually recognized as the scientific literature evolves.

When we began developing Acapodene 20 mg for the prevention of prostate cancer in men with high grade PIN in the 1990s, clinicians and investors had questions around the relevance of high grade PIN. No drugs were on the market for treating premalignant lesions. We chose men with high grade PIN because we believe high risk patients are the proper subjects of prevention drug development programs. There is no longer controversy that high grade PIN is the premalignant lesion of prostate cancer. With studies showing that men with high grade PIN are at greater risk for prostate cancer, the challenge is understanding how to follow these patients and when to intervene. In a Phase IIb clinical trial, Acapodene 20 mg reduced prostate cancer risk. Acapodene 20 mg is now being evaluated in a Phase III clinical trial which will define its role in prostate cancer prevention. Today, the climate is different, as large pharmaceutical companies have approved drugs for cancer prevention targeting premalignant lesions, such as Nolvadex® for DCIS, Celebrex® for familial adenomatous polyposis, and the cervical cancer HPV vaccine Gardasil®, which reduces CIN, or cervical intraepithelial neoplasia.

When we began developing Acapodene 80 mg for the treatment of side effects of ADT, androgen deprivation therapy was a relatively new treatment and was heralded along with early detection for a dramatic improvement in observed survival rates. Few researchers were focused on the serious and potentially life threatening side effects of long-term ADT, such as osteoporosis and increased risk of fractures, adverse lipid changes and increased cardiovascular risk, as well as the symptomatic side effects, hot flashes and gynecomastia. These side effects are now well recognized and may lead patients to be non-compliant with their cancer therapy. In early 2008, we announced that in the Phase III ADT clinical trial, Acapodene 80 mg as a daily oral dose reduced vertebral fractures, the primary endpoint of the trial, and also increased bone mineral density, reduced hot flashes, ameliorated gynecomastia, and improved lipid profiles. Acapodene 80 mg, which binds to and selectively

modulates the estrogen receptor depending on tissue type, addressed the multiple estrogen related side effects of ADT.

In both cases, the scientific progress in the field has paralleled our clinical development and now supports our original clinical beliefs. At GTx, we believe if we stand firm by our independent scientific vision, we will be positioned to deliver new medicines to patients years ahead of the competition.

*The importance of the right partner and the right deal*

For GTx, the hallmark of 2007 was the unique strategic collaboration we formed in November with Merck for the discovery, development and global commercialization of SARMs.

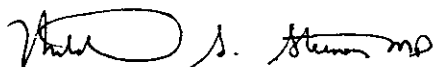
After we announced in December 2006 the positive results of the Phase II Ostarine™ clinical trial, which demonstrated the ability of our lead SARM to build muscle and improve physical performance, we attracted strong interest from a number of large pharmaceutical and biotechnology firms. In the end, we chose to enter into a strategic collaboration with Merck for all of the right reasons. Merck has an advanced internal SARM program, and our scientific teams believe we will work well together and bring complementary strengths. Merck also has the vision and the experience necessary to develop and commercialize a new drug class in a new therapeutic area. Importantly, Merck recognizes GTx's deep expertise in the discovery and development of SARMs and has agreed to pool its program and drug candidates with ours in a deal that provides GTx with equivalent milestone payments and royalties, regardless of which company's molecules move forward. This unique structure will permit scientific merit and commercial opportunity to drive SARMs research forward. In our first few meetings together as partners, it has been clear that Merck shares our excitement and urgency to capitalize on our collaboration's advantage developing SARMs to treat frailty or sarcopenia, cancer cachexia and other indications well in advance of other companies working in the SARM field.

We are also excited to have Ipsen as our partner for the development and commercialization of Acapodene in Europe. Ipsen has scientific strength in endocrinology and oncology, and their drug Decapeptyl® has a large share of the androgen deprivation therapy market in Europe. Ipsen understands the need for a drug like Acapodene 80 mg to treat the side effects of ADT and knows the potential of Acapodene 20 mg to prevent prostate cancer. Ipsen has the regulatory capability to bring Acapodene through the marketing approval process in Europe and the commercial relationships to make it a success.

*The right team for the next ten years*

We have and will continue to attract and recruit a talented team of scientists, clinicians, regulatory experts, and business leaders to Memphis. Our next decade brings with it new opportunities as we stand on the cusp of commercializing Acapodene. We have achieved much in our first ten years—as we look ahead we will remain a science driven organization that is intensely focused on the discovery, development, and now the commercialization of important selective small molecules to modulate hormone pathways to address unmet medical diseases.

Yours truly,



Mitchell S. Steiner, MD, FACS  
Vice Chairman and Chief Executive Officer

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2007

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-50549

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

3 N. Dunlap Street

Van Vleet Building

Memphis, Tennessee

(Address of principal executive offices)

62-1715807

(I.R.S. Employer Identification No.)

38163

(Zip Code)

(901) 523-9700

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001 per share	The NASDAQ Stock Market, LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

SEC  
Mail Processing  
Section

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Washington, DC  
104

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).  
Yes ☐ No ☒

The aggregate market value of common stock held by non-affiliates of the registrant based on the closing sales price of the registrant's common stock on June 29, 2007 as reported on the NASDAQ Global Market was \$199,944,800.

There were 36,236,263 shares of registrant's common stock issued and outstanding as of March 5, 2008.

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## **DOCUMENTS INCORPORATED BY REFERENCE**

Certain portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the Registrant's 2008 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include statements about:

- the anticipated progress of our and our collaborators' research, development and clinical programs, including whether future clinical trials will achieve similar results to clinical trials that we have successfully concluded;
- potential future licensing fees, milestone payments and royalty payments including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Ipsen Limited and Merck & Co., Inc.;
- our and our collaborators' ability to market, commercialize and achieve market acceptance for our product candidates or products that we and/or our collaborators may develop;
- our and our collaborators' ability to generate additional product candidates for clinical testing;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources.

In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks, uncertainties and other important factors. We discuss many of these risks, uncertainties and other important factors in this Annual Report on Form 10-K in greater detail in the section entitled "Risk Factors" under Part I, Item 1A below. Given these risks, uncertainties and other important factors, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K and the documents that we incorporate by reference in and have filed as exhibits to this Annual Report on Form 10-K, completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.



## PART I

### ITEM 1. BUSINESS

#### Overview

GTx, Inc., a Delaware corporation incorporated on September 24, 1997, is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. In February 2008, we announced that the Phase III clinical trial results for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT showed that ACAPODENE® 80 mg reduced new morphometric vertebral fractures and met other key endpoints of bone mineral density, or BMD, lipid profiles and gynecomastia. In March 2008, we announced that the results from this Phase III clinical trial also showed that ACAPODENE® 80 mg demonstrated a reduction in hot flashes in a subset analysis. We expect to file a New Drug Application, or NDA, for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT with the U.S. Food and Drug Administration, or FDA, in 2008. We have licensed to Ipsen Limited, or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we collectively refer to as the European Territory, to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which we have licensed from Orion Corporation, or Orion, which include all indications in humans except breast cancer outside of the United States. In addition to ACAPODENE®, we are developing selective androgen receptor modulators, or SARMs, with Merck and Co., Inc., or Merck. In November 2007, we entered into an exclusive license and collaboration agreement with Merck establishing a global strategic collaboration for the discovery, development and commercialization of SARMs, including Ostarine™. We believe that Ostarine™ and other SARM candidates, including GTx-838, have the potential to treat a variety of indications associated with muscle wasting and bone loss, including frailty, muscle loss associated with aging, also known as sarcopenia, muscle wasting in cancer patients, known as cancer cachexia, osteoporosis, and chronic kidney disease muscle wasting. We are currently evaluating Ostarine™ in a Phase II clinical trial for the treatment of cancer cachexia.

We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the FDA for the treatment of metastatic breast cancer in postmenopausal women in the United States. In January 2005, we acquired from Orion the right to market FARESTON® tablets in the United States for the metastatic breast cancer indication. We also acquired from Orion a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. The active pharmaceutical ingredient in FARESTON® is the same as in ACAPODENE®, but in a different dose. We plan to build specialized sales and marketing capabilities to promote our product candidates to urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates in broader markets in the United States and in the rest of the world.

We also have an extensive preclinical pipeline generated from our own discovery program, including GTx-758, an oral luteinizing hormone, or LH, inhibitor being developed for the treatment of advanced prostate cancer, and GTx-878, an estrogen receptor beta agonist, a new class of drugs being developed for the treatment of benign prostatic hyperplasia, or BPH. We are planning to initiate Phase I clinical testing for GTx-758 by the end of 2008 and for GTx-878 in the first half of 2009.

Our most advanced product candidate, ACAPODENE®, is being developed to treat multiple serious side effects of ADT and to prevent prostate cancer in high risk men with high grade PIN. ADT is the most common treatment for advanced, recurrent or metastatic prostate cancer, and we believe that it is currently used to treat approximately 800,000 men in the United States. ADT is hormone therapy that works by reducing testosterone and estrogen. The low estrogen levels unintentionally caused by ADT can lead to multiple serious side effects including: severe bone

loss, or osteoporosis, resulting in skeletal fractures; hot flashes; lipid profile changes that lead to higher rates of cardiovascular disease; and breast pain and enlargement, or gynecomastia. There are currently no drugs approved by the FDA for the treatment of these multiple serious side effects of ADT. We commenced a pivotal Phase III clinical trial of ACAPODENE® 80 mg under a Special Protocol Assessment, or SPA, with the FDA for this indication in November 2003. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the agency to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. The primary endpoint was new morphometric vertebral fractures measured by x-ray, and the secondary endpoints included BMD, lipid profile changes, gynecomastia and hot flashes. The last patient completed the ADT clinical trial in November 2007. In February 2008, we announced that the results of the Phase III clinical trial showed that ACAPODENE® 80 mg reduced new morphometric vertebral fractures and met other key endpoints of BMD, lipid profiles and gynecomastia. Also, in March 2008, we announced that the results from this Phase III clinical trial of ACAPODENE® 80 mg demonstrated a reduction in hot flashes. We expect to file a NDA for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT with the FDA in 2008.

In the United States, prostate cancer is one of the most commonly diagnosed cancers and the second leading cause of cancer-related deaths in men. Men who have high grade PIN are at high risk of developing prostate cancer (we believe that more than 40% of men with high grade PIN detected on a prostate biopsy develop prostate cancer within three years). In the United States, there are over 115,000 new cases of high grade PIN diagnosed each year and an estimated 14 million men under the age of 80 may unknowingly harbor this condition. Currently, there is no approved treatment to prevent prostate cancer in high risk men with high grade PIN. In January 2005, we initiated a pivotal Phase III clinical trial of orally administered ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a SPA with the FDA. We will evaluate efficacy endpoints for the clinical trial at 36 months after completion of enrollment, and we anticipate conducting a planned efficacy interim analysis after a certain number of cancer events have been recorded among study patients, which we currently expect to occur by the end of the first quarter of 2008. If the efficacy results from the planned interim analysis achieve the statistical outcome specified in the SPA ( $\alpha \leq 0.001$ ), we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the efficacy interim analysis, we will continue to collect efficacy data and safety data during the review process to satisfy the FDA's safety requirements set forth in the SPA. If the efficacy results from the planned interim analysis do not satisfy the specified statistical requirements in the SPA, we plan to continue the clinical trial.

In our third clinical program, Ostarine™, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss. In December 2006, we announced that Ostarine™ met its primary endpoint in a Phase II proof of concept, double blind, randomized, placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. We initiated a Phase II randomized, double blind, placebo controlled clinical trial evaluating Ostarine™ for the treatment of cancer cachexia in 150 patients diagnosed with non-small cell lung cancer, colorectal cancer, non-Hodgkin's lymphoma, or chronic lymphocytic leukemia. The clinical trial is being conducted at approximately 50 clinical sites in the United States, Argentina and Canada and we expect to receive data from this trial during the summer of 2008.

In November 2007, we entered into an exclusive license and collaboration agreement with Merck which governs our and Merck's joint research, development and commercialization of SARM compounds and related SARM products, including SARMS currently being developed by us and Merck and those yet to be discovered, for all potential indications of interest. Under the agreement, we will conduct preclinical research of SARM compounds and products, and Merck will be primarily responsible for conducting and funding development and commercialization of products developed under the agreement. We received an upfront licensing fee of \$40.0 million in January 2008 and Merck has agreed to pay us \$15.0 million in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the agreement. We are also eligible to receive up to \$422.0 million in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine™, as defined in the agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the agreement, upon the achievement of such development and regulatory approval milestones and assuming the continued effectiveness of the agreement. Merck also has agreed to pay us tiered royalties on net sales of products that may be developed under the agreement. On the date the agreement became effective in December 2007, we issued to Merck 1,285,347 newly-issued shares of our common stock for an

aggregate purchase price of approximately \$30.0 million. We and Merck, through our SARM collaboration, will determine the development strategy of Ostarine™, GTx-838 and other collaboration compounds.

In September 2006, we entered into a collaboration and license agreement with Ipsen pursuant to which we granted Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE® and other products containing toremifene in all indications that we have licensed from Orion. In accordance with the terms of the agreement, Ipsen paid us €21.5 million as a license fee and expense reimbursement and is paying us €1.5 million in equal installments over a three year period from the date of the agreement. Pursuant to the agreement, we are also entitled to receive from Ipsen up to an aggregate of €39.0 million in milestone payments depending on the successful development and launch of ACAPODENE® in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. Ipsen has agreed to be responsible for and to pay for all clinical development, regulatory and launch activities to commercialize ACAPODENE® in the European Territory for both the high grade PIN indication and the ADT indication. We will remain similarly responsible for all development and regulatory activities outside of the European Territory. However, Ipsen has agreed to pay a portion of our ACAPODENE® development costs in the United States if certain conditions are met. Under the agreement, Ipsen must elect to retain its rights to commercialize ACAPODENE® and other products containing toremifene for the high grade PIN indication. Until such time as Ipsen shall make its election, however, it is required to initiate and carry out the development of ACAPODENE® for the high grade PIN indication in the European Territory and to pay all costs associated therewith.

### **Scientific Background on Estrogens and Androgens**

Both estrogens and androgens are hormones that play critical roles in men's and women's health, regulating not only the reproductive system, but also having important effects on the muscular, skeletal, cardiovascular, metabolic and central nervous systems. In order for the body to function properly, a balance must exist between estrogens and androgens.

Estrogens prevent osteoporosis, reducing the risk of skeletal fractures, may be cardioprotective by having a favorable effect on lipid profile and may reduce hot flashes. As testosterone levels decrease in aging men, there is also a gradual increase in estrogen levels in the blood relative to testosterone levels which may promote BPH, initiate prostate cancer and cause gynecomastia.

Testosterone, the predominant androgen in men, is important for mental well-being and for masculine physical characteristics, such as muscle size and strength and bone strength. Male reproductive health is also dependent on testosterone to maintain sexual interest, fertility, erectile function and normal prostate function. Testosterone is converted into a more potent androgen, dihydrotestosterone, or DHT, which also stimulates sebaceous and hair glands and may cause unwanted effects like acne and hair loss. DHT is the primary androgen involved in BPH. In aging men, there is a gradual decline in testosterone levels, which contributes to a loss of muscle mass and strength, and decreased bone mineralization, which may result in osteoporosis and bone fractures, erectile dysfunction, decreased sexual interest, depression and mood changes.

Estrogens and androgens perform their physiologic functions by binding to and activating their hormone receptors located in various tissues. Once a hormone binds with its receptor, this activates a series of cellular events that results in estrogenic or androgenic tissue effects.

Pharmaceuticals that target estrogen or androgen receptors have been used medically for over 50 years. The drugs that have been used to stimulate androgen receptors are either natural or synthetic hormones, known as steroids. Steroids activate hormone receptors in all tissue types in a non-selective manner resulting in not only beneficial effects but also in unwanted clinical effects. In men, the absence of selectivity and conversion of testosterone to DHT may result in unwanted side effects, such as the potential stimulation of latent into clinical prostate cancer, and may enhance BPH, cause acne, cause loss of hair in men and hair growth in women and cause gynecomastia. Currently, no orally available testosterone products have been approved for use in the United States, and those testosterone products that are available must be administered by intramuscular injections or by transdermal patches or gels that may not be convenient for patients and, in some cases, can result in inconsistent blood levels of testosterone.

There are also classes of small molecules that are not steroids that can bind to the same hormone receptors. These nonsteroidal small molecules may either stimulate or block hormone receptors depending on the type of tissue in which the receptor is found and the interaction of the small molecule with the receptor. A drug that has the ability to either block or stimulate the hormone receptor is called a selective hormone receptor modulator. A selective hormone receptor modulator that can either block or stimulate a hormone receptor in a tissue-selective manner may be able to mimic the beneficial, while minimizing the unwanted, effects of natural or synthetic steroid hormones.

A SERM is a nonsteroidal small molecule that binds to and selectively modulates estrogen receptors. SERMs have the ability to either stimulate or block estrogen's activity in different tissue types. SERMs have been shown to mimic estrogen's beneficial action in bone and lipid profiles, and we believe that SERMs have the potential to block estrogen's harmful activity in the prostate and the breast. Examples of SERMs currently on the market include toremifene, which is FDA approved to treat advanced female breast cancer, and raloxifene, which is used to prevent and treat postmenopausal female osteoporosis.

A SARM is a small molecule that binds to and selectively modulates androgen receptors, the primary receptor to which testosterone binds. In men, SARMs potentially have beneficial action in bone and muscle while blocking testosterone's unwanted action in the prostate and skin. We further believe that SARMs can be designed to either cross or not cross into the central nervous system and to selectively modulate androgen receptors in the brain to affect mood and sexual interest. Although no SARMs have been commercialized to date, we believe that SARMs without testosterone's or other exogenous anabolic steroid therapies' harmful side effects can be developed to treat a range of medical conditions, including: (1) muscle wasting conditions of chronic diseases, such as cancer, AIDS, chronic kidney disease, end-stage renal disease, neurodegenerative disorders, trauma and burns; (2) muscle wasting conditions associated with aging such as frailty and sarcopenia; (3) the prevention and/or treatment of osteoporosis; (4) prostate disorders, such as BPH and prostate cancer; (5) disorders of the central nervous system, such as low libido, depression and other mood disorders; (6) low testosterone conditions, such as primary and secondary hypogonadism; (7) male reproductive functions, such as infertility, male contraception and erectile dysfunction; and (8) other conditions, such as anemia and male hair loss.

### **Marketed Product**

#### **FARESTON®**

We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the FDA for the treatment of metastatic breast cancer in postmenopausal women in the United States. Toremifene is a SERM owned and manufactured by Orion. On January 1, 2005, we entered into a revised license and supply agreement with Orion to exclusively license toremifene for all indications in the United States and for all indications in humans except breast cancer outside of the United States. Toremifene is the active pharmaceutical ingredient in ACAPODENE®, our lead product candidate currently in two separate clinical programs for two indications, and FARESTON®.

We currently sell FARESTON® primarily through wholesale drug distributors. The top three distributors, McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation, accounted for approximately 93% of our gross product sales generated from the sale of FARESTON® for the year ended December 31, 2007. The loss of any of these three distributors could have a material adverse effect on continued FARESTON® sales. FARESTON® net product sales accounted for 15%, 18% and 65% of our total revenue for the years ended December 31, 2007, 2006 and 2005, respectively.

## Product Candidates

The following table identifies the development phase and status for each of our product candidates:

Program	Product Candidate/ Indication	Development Phase	Status
<b>Clinical</b>			
<b>SERM</b>	<b>ACAPODENE®</b> <b>80 mg</b> Multiple serious side effects of ADT	Pivotal Phase III clinical trial	Phase III clinical trial, which was conducted under a SPA, completed in February 2008; achieved primary endpoint of reduction of new morphometric vertebral fractures
	<b>ACAPODENE®</b> <b>20 mg</b> Prevention of prostate cancer in high risk men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; attained enrollment goal; planned efficacy interim analysis by the end of the first quarter 2008
<b>SARM</b>	<b>Ostarine™</b> Cancer cachexia	Phase II clinical trial	Phase II proof of concept clinical trial completed in December 2006; Phase II clinical trial to treat cancer cachexia ongoing
<b>Preclinical</b>			
<b>SARM</b>	<b>GTx-838</b>	Preclinical	We and Merck, through our SARM collaboration, will determine the clinical development strategy of GTx-838
<b>LH inhibitor</b>	<b>GTx-758</b> Advanced Prostate Cancer	Preclinical	Phase I clinical testing planned by the end of 2008
<b>Estrogen receptor beta agonist</b>	<b>GTx-878</b> BPH	Preclinical	Phase I clinical testing planned in the first half of 2009

### ACAPODENE® (toremifene citrate)

Our most advanced product candidate, ACAPODENE®, is a SERM. ACAPODENE® is being developed as a once-a-day oral tablet to (1) treat multiple serious side effects of ADT (80 mg dose) and (2) prevent prostate cancer in high risk men (20 mg dose). In January 2005, we exclusively licensed toremifene, the active ingredient in ACAPODENE®, for all indications in humans, except breast cancer outside of the United States. We licensed rights to toremifene based on our belief that a SERM can treat estrogen related complications resulting from ADT and reduce the incidence of prostate cancer in high risk men with high grade PIN and toremifene's established record of safety in the treatment of postmenopausal women with advanced breast cancer. Under a license and supply agreement with Orion, Orion manufactures and supplies us with FARESTON®, the 60 mg dose of toremifene citrate, for sale in the United States to treat advanced breast cancer, as well as ACAPODENE® 20 mg dose of toremifene

citrate for our Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade PIN.

In September 2006, we licensed to Ipsen exclusive rights to develop and commercialize ACAPODENE® and other products containing toremifene in the European Territory in all indications that we have licensed from Orion.

### ***ACAPODENE® 80 mg for the Treatment of Multiple Serious Side Effects of ADT***

**Scientific Overview.** ADT is the most common treatment for patients who have advanced, recurrent or metastatic prostate cancer. ADT reduces testosterone, a primary growth factor for prostate cancer, to levels similar to that of castrated men. ADT is accomplished either surgically by removal of the testes, or chemically by treatment with LH releasing hormone agonists, or LHRH agonists. LHRH agonists work by shutting off LH secretion by the pituitary gland, which stops testosterone production by the testes. Examples of commercially marketed LHRH agonists are Lupron® (leuprolide acetate), Zoladex® (goserelin acetate), Viadur® (leuprolide acetate) and Eligard® (leuprolide acetate). The reduction in testosterone from ADT also results in very low estrogen levels in men, because estrogen is derived from testosterone in men.

Estrogen related side effects associated with ADT include bone loss, which may lead to osteoporosis and skeletal fractures, hot flashes, gynecomastia, adverse lipid changes that may lead to higher risk of cardiovascular diseases, depression, and memory loss. Bone loss leading to osteoporosis and possible skeletal fractures is a significant clinical problem because clinical studies have shown that prostate cancer patients who develop skeletal fractures have 39 month shorter survival rates. Hot flashes occur because of reduced estrogen levels in the brain. Hot flashes experienced by prostate cancer patients on ADT tend to be severe, frequent and protracted and is the side effect most frequently mentioned by prostate cancer patients on ADT.

Based on the results of our Phase III clinical trial, our two Phase II clinical trials and our preclinical testing of ACAPODENE® 80 mg, as well as preclinical and clinical information known about toremifene, ACAPODENE® has estrogenic activity both in bone, which treats osteoporosis, and in the brain, which may reduce hot flashes. Toremifene has been shown to improve lipid profiles in postmenopausal women and, based on data received from our Phase III clinical trial, ACAPODENE® improves lipid profiles in men undergoing androgen deprivation therapy for prostate cancer. ACAPODENE® also can block estrogen's action in the male breast, which may prevent and treat gynecomastia. As a consequence, we believe that ACAPODENE® 80 mg has the potential to treat serious estrogen related side effects of LHRH agonists: osteoporosis and fractures, hot flashes, adverse lipid changes and gynecomastia. Importantly, as evidenced by our two Phase II clinical trials and our Phase III clinical trial, ACAPODENE® has not been shown to stimulate prostate cancer growth or increase luteinizing hormone in men on ADT.

**Potential Market.** In the United States, we believe approximately 800,000 prostate cancer patients are currently being treated with ADT, and over 100,000 new patients are started on this therapy each year. An increasing number of prostate cancer patients are being treated by androgen deprivation with LHRH agonists earlier than in the past because of two main factors: first, medical studies have shown that early ADT prolongs the survival of prostate cancer patients, and second, the serum test for prostate specific antigen, or PSA, is detecting advanced prostate cancer earlier than in the past. The net effect of prostate cancer being treated sooner and for longer periods is that the multiple serious side effects of ADT have now been shown to contribute significantly to morbidity, and in some cases may lead to increased mortality. Physicians are currently prescribing certain drugs on an off-label basis to help ameliorate some of the specific serious side effects of ADT. These drugs include bisphosphonates for osteoporosis, Megace® (megestrol acetate) and antidepressants for hot flashes and tamoxifen for gynecomastia. Radiation is also used to treat gynecomastia. However, no single therapy is available to treat multiple serious side effects of ADT.

**Clinical Trials.** We have completed two Phase II clinical trials of ACAPODENE® for the treatment of osteoporosis and hot flashes in patients with advanced, recurrent or metastatic prostate cancer. The first Phase II trial was conducted at five clinical sites across the United States and treated 43 patients with advanced, recurrent or metastatic prostate cancer shortly after initiation of treatment with LHRH agonists. The second of these trials was conducted at three clinical sites across the United States and treated 46 patients with advanced, recurrent or metastatic prostate cancer who had been receiving LHRH agonists for more than 12 months. In each trial, participants were randomized to either a daily oral dose of ACAPODENE® or a placebo for six months. The

primary endpoint of both trials was BMD. The secondary endpoint of both trials was the incidence of hot flashes. We measured BMD and hot flash symptoms at entry into each of the clinical trials and at six months. We did not evaluate the effects of ACAPODENE® on gynecomastia in either of these trials.

In our first Phase II clinical trial, which evaluated 43 patients shortly after initiation of treatment with LHRH agonists, patients who received ACAPODENE® at the highest tested dose on average experienced an approximately 2% decrease in lumbar vertebral spine BMD at six months, while the patients who received the placebo on average experienced an approximately 4% decrease in lumbar vertebral spine BMD at six months. At the lower tested doses, ACAPODENE®, as compared to the placebo, did not have a meaningfully different effect on lumbar vertebral spine BMD. There was no significant difference between ACAPODENE® and the placebo in the incidence of hot flashes at any tested dose.

In our second Phase II clinical trial, which evaluated 46 patients who had been receiving LHRH agonists for more than 12 months, patients who received ACAPODENE® at the highest tested dose experienced a 3.5% average increase in lumbar vertebral spine BMD, an indicator of bone strength, while the patients who received the placebo experienced a 0.24% average increase in lumbar vertebral spine BMD. The difference in these measurements had a p-value of less than 0.05. A p-value of 0.05 or less generally represents a statistically significant difference in treatments. The BMD changes in the hip were not significant vs. placebo. Only 12.5% of the patients in this trial who received ACAPODENE® at the highest tested dose, compared to 50% of the patients who received the placebo, reported experiencing an increase in the frequency of hot flashes during the clinical trial. The magnitude of the BMD changes seen in patients treated with ACAPODENE® in this Phase II clinical trial were similar to those reported for each of raloxifene and bisphosphonates in postmenopausal women with osteoporosis and bisphosphonates being prescribed off-label to men with prostate cancer. However, bisphosphonates have not been shown to have any effect on hot flashes or gynecomastia. At the lower tested doses, ACAPODENE®, compared to the placebo, did not demonstrate a meaningful effect on lumbar vertebral spine BMD or frequency of hot flashes.

In November 2003, we initiated a pivotal Phase III clinical trial of orally administered ACAPODENE® 80 mg dose in patients undergoing ADT for advanced, recurrent or metastatic prostate cancer under a SPA, from the FDA. We designed this pivotal Phase III clinical trial principally based on the results of our second Phase II clinical trial that evaluated patients who had been receiving LHRH agonists for more than 12 months. The primary endpoint of the trial was new morphometric vertebral fractures measured by x-ray, and the secondary endpoints of the trial included BMD, hot flashes, lipid profile changes and gynecomastia. We reached our enrollment goal in the fall of 2005 and randomized approximately 1,400 patients into the trial with advanced, recurrent or metastatic prostate cancer who had been receiving ADT for at least six months and who had significant existing bone loss, or were greater than 70 years of age. The patients were randomized to receive either a placebo or a daily 80 mg dose of ACAPODENE® for 24 months. We conducted the trial in approximately 150 sites in the United States and Mexico. In December 2005 and in accordance with the SPA, we completed a planned interim BMD analysis among the first 197 patients who completed one year of treatment. Patients treated with ACAPODENE® 80 mg demonstrated statistically significant increases in BMD compared to placebo in all three skeletal sites measured, with lumbar spine showing an improvement of 2.3 percentage points ( $p < 0.001$ ), hip, a 2.0 percentage point improvement ( $p = 0.001$ ), and femoral neck, a 1.5 percentage point improvement ( $p = 0.009$ ). For perspective, a study of raloxifene, a SERM, in postmenopausal osteoporosis in women showed a lumbar spine BMD increase of 2.0 percentage points after one year which resulted in a 55% fracture reduction in three years. In June 2006, we conducted a lipid interim analysis of the same 197 patients. Patients treated with ACAPODENE® 80 mg had statistically significant lower levels of total cholesterol, LDL, and triglycerides, reduction in the ratio of total cholesterol to HDL, and higher levels of HDL, when compared to patients on placebo.

A Data Safety Monitoring Board, or DSMB, meets every six months to review unblinded data from the ACAPODENE® 80 mg ADT and ACAPODENE® 20 mg PIN clinical trials. In January 2007 and July 2007, the DSMB reviewed safety data from approximately 2,900 and 3,000 patients, respectively, and recommended to continue both trials.

The last patient completed the ADT clinical trial in November 2007. In February 2008, we announced that the Phase III clinical trial results for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT showed that ACAPODENE® 80 mg reduced new morphometric vertebral fractures and met other key endpoints of BMD, lipid profiles and gynecomastia. In the modified intent to treat analysis which included all patients with at

least one evaluable study radiograph and a minimum of one dose of study drug or placebo, ACAPODENE® 80 mg demonstrated a 50% reduction in new morphometric vertebral fractures ( $p < 0.05$ ; 5% fracture rate in the placebo group). The estimated two year fracture rate for new morphometric vertebral fractures in the placebo group was 6.2%. In an intent to treat analysis which included all patients randomized into the trial, ACAPODENE® 80 mg demonstrated a 53% reduction in new morphometric vertebral fractures ( $p = 0.034$ ; 3.6% fracture rate in the placebo group). In prespecified subset analyses, in study patients who were greater than 80% treatment compliant, ACAPODENE® 80 mg reduced new morphometric vertebral fractures by 61% ( $p = 0.017$ ). When study patients who had greater than 7% bone loss at one year and new morphometric vertebral fractures were considered as treatment failures, ACAPODENE® 80 mg compared to placebo demonstrated a 56% reduction ( $p = 0.003$ ).

Patients treated with ACAPODENE® 80 mg compared to placebo demonstrated statistically significant increases in BMD in the lumbar spine, hip, and femur skeletal sites (each site demonstrating  $p < 0.0001$ ). ACAPODENE® 80 mg treatment compared to placebo also resulted in a decrease in total cholesterol ( $p = 0.011$ ), LDL ( $p = 0.018$ ), and triglycerides ( $p < 0.0001$ ), and an increase in HDL ( $p = 0.001$ ). There were also statistically significant improvements in gynecomastia ( $p = 0.003$ ). In March 2008, we announced that in an analysis of hot flashes in a subset of patients in the Phase III ADT clinical trial experiencing six or more hot flashes per day at baseline and not being treated with megestrol acetate (Megace(R)), ACAPODENE® 80 mg treatment reduced the number of hot flashes by an average of 4.7 hot flashes per day compared to placebo patients who had a reduction of 1.6 hot flashes per day ( $p = 0.03$ ). The reduction of hot flashes in patients treated with ACAPODENE® 80 mg was durable for at least 12 months.

ACAPODENE® 80 mg had a favorable safety profile and was well tolerated. Among the most common adverse events that occurred in over 2% of study subjects were joint pain (treated 7.3%, placebo 11.8%), dizziness (treated 6.3%, placebo 5.0%), back pain (treated 5.9%, placebo 5.2%), and extremity pain (treated 5.0%, placebo 4.4%). Venous thromboembolic events, or VTEs, which included both deep venous thrombosis and pulmonary embolism, were 17 (2.4 %) in the ACAPODENE® 80 mg treated group and 7 (1.02 %) in the placebo group. The risk for VTE's was similar between the ACAPODENE® 80 mg treated group and the placebo group in the second year of treatment. The majority of VTEs occurred in men at high risk for a VTE including: age  $> 80$  years or history of VTE. In men without major risk factors for VTE, there were 3 (1.3%) VTE in the ACAPODENE® 80 mg treated group and 2 (1.0%) VTE in the placebo group.

**NDA Filing.** We expect to file a NDA for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT with the FDA in 2008.

#### ***ACAPODENE® 20 mg for the Prevention of Prostate Cancer in High Risk Men with High Grade PIN***

**Scientific Overview.** Patients who have an abnormal serum PSA test, a prostate cancer blood test that is commonly administered to men as part of physical examinations, or an abnormal digital rectal examination routinely undergo a prostate biopsy to determine whether they have prostate cancer. Precancerous prostate lesions known as high grade PIN, rather than prostate cancer, are detected in approximately 15% of the patients who undergo prostate biopsies. Over the last 17 years, scientific evidence has established that men who have high grade PIN are at high risk for developing prostate cancer. More than 40% of these men will progress to prostate cancer within three years. We believe that this strong correlation between high grade PIN and prostate cancer makes these men an appropriate population to treat to prevent prostate cancer. Currently, there is no approved treatment to prevent prostate cancer in men who are diagnosed with high grade PIN.

Testosterone and estrogens together are important for the initiation of prostate cancer. Estrogens may promote the development of prostate cancer by stimulating high grade PIN and causing it to progress into prostate cancer. Estrogen receptors are found in the normal prostate and in high grade PIN lesions. In animal models of prostate cancer, blocking estrogens' action has been shown to reduce the incidence of prostate cancer. Because ACAPODENE® blocks estrogen receptors, we believe that it has the potential to reduce the incidence of prostate cancer in high risk men with high grade PIN.

**Potential Market.** In the United States, prostate cancer is one of the most commonly diagnosed cancers and the second leading cause of cancer-related deaths in men. There are approximately 186,000 new cases of prostate cancer diagnosed each year and 27,000 prostate cancer deaths annually in the United States. In addition, there are over 115,000 new cases of high grade PIN diagnosed each year, with an estimated 14 million men under the age of



80 who unknowingly harbor high grade PIN.

Patients who are diagnosed with high grade PIN may undergo repeat biopsies following the diagnosis in order to detect the progression of high grade PIN into prostate cancer. Prostate biopsies are performed through an ultrasound probe placed in the rectum. Hollow needles are then inserted through the probe through the rectum into the prostate to obtain sample cores of tissue. Complications from this procedure include bleeding, pain, prostate infection and, in rare instances, life-threatening blood infection (sepsis). Because the prostate biopsy technique randomly samples the prostate gland with a relatively thin needle, both prostate cancer and high grade PIN may be missed by the biopsy. Patients with high grade PIN are exposed to the potential complications and the discomfort of invasive, repeat prostate biopsies and are subject to the mental anguish of fearing that a diagnosis of prostate cancer may be imminent.

We have entered into separate collaboration agreements with diagnostic companies, including Hybritech, Inc., a wholly owned subsidiary of Beckman Coulter, Inc., diaDexus, Inc., MacroArray Technologies, LLC, Onconome, Inc. (formerly known as Tessera, Inc.), and Gen-Probe, Inc., to provide clinical samples to these companies from our Phase IIb clinical trial and our ongoing Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN. Information resulting from these collaborations will be used to evaluate whether a commercial test using blood or urine may be effectively developed to detect high grade PIN and/or prostate cancer. By continuing to collaborate with leading diagnostic labs, we hope to have a urine or blood test developed to detect high grade PIN in the millions of American men who may unknowingly harbor high grade PIN and/or prostate cancer.

**Clinical Trials.** In 2004, we completed a randomized, double blind, placebo controlled, dose finding Phase IIb clinical trial of ACAPODENE® in men diagnosed with high grade PIN to determine the efficacy and safety of a daily dose of ACAPODENE® for 12 months. The trial enrolled 514 men and was conducted at 64 clinical sites across the United States. The primary efficacy endpoint of this trial was incidence of prostate cancer at 12 months. Participants were randomized to receive a 20 mg, 40 mg or 60 mg dose of ACAPODENE® or placebo. A screening prostate biopsy was performed on each trial participant before enrollment into the trial, and eligibility was limited to participants who were diagnosed with high grade PIN and had no evidence of prostate cancer. A second biopsy was performed six months after enrollment in an effort to identify trial participants who had prostate cancer that was not detected by the initial biopsy. The intent to treat population consisted of all patients initially enrolled in the trial who returned for their six-month biopsy. We also analyzed trial results in a predefined subgroup of patients that excluded patients showing biopsy evidence of prostate cancer at six months and patients who did not complete the full course of therapy in the trial (completer's analysis).

We analyzed the results of this Phase IIb clinical trial on a stratified basis, in which we assessed the effect of individual clinical sites on the overall statistical analysis of the trial results, and on an unstratified basis, in which we did not assess such effect. In the stratified analysis of the per protocol population, which is the intent to treat population less two patients in the group that received 20 mg of ACAPODENE® who were deemed to be not compliant with the protocol, the cumulative, or overall, risk of prostate cancer was 24.4% in the group that received 20 mg of ACAPODENE® compared with 31.2% in the group that received placebo. The p-value for this result was less than 0.05. Thus, the cumulative risk of prostate cancer based on a stratified analysis of the per protocol population was 22.0% lower in the 20 mg treatment group, which would imply an annualized rate of prevention of cancers of 6.8 per 100 men treated. The p-value in the unstratified analysis of the per protocol population for the comparison between the group that received 20 mg of ACAPODENE® and the group that received placebo was 0.132. In the stratified analysis of the intent to treat population, the cumulative risk of prostate cancer was 24.9% in the group that received 20 mg of ACAPODENE® compared with 31.2% in the group that received placebo. The p-value for this result was 0.081, which was statistically significant under the protocol for this trial. Statistical significance under the protocol was defined as a p-value of 0.10 or less. The p-value in the unstratified analysis of the intent to treat population for the comparison between the group that received 20 mg of ACAPODENE® and the group that received placebo was 0.148.

In a stratified analysis of the subgroup of patients who had no biopsy evidence of prostate cancer at their initial screening biopsy or their six-month biopsy and completed the full course of therapy in the trial, the cumulative risk of prostate cancer was 9.1% in the group that received 20 mg of ACAPODENE® compared with 17.4% in the group that received placebo, a 48.2% reduction. The p-value for this result was less than 0.05. For the 40 mg and 60 mg

treatment arms, in the intent to treat population, the per protocol population and the predefined patient subgroup, the cumulative risk of cancer was lower than the placebo group, although these results were not statistically significant.

The overall rates of drug-related adverse events and serious adverse events did not differ to a significant degree between any of the ACAPODENE® dose groups and placebo. The results of our pivotal Phase III clinical trial of ACAPODENE® 20 mg for this indication may not be the same as the results of this Phase IIb clinical trial.

In January 2005, we initiated a randomized, double blind, placebo controlled pivotal Phase III clinical trial of orally administered ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a SPA with the FDA. Approximately 130 clinical sites across the United States and Canada are participating in this trial. We have randomized a total of 1,590 patients into the trial, 330 patients above our enrollment goal of 1,260 patients. These additional patients are also participating in bone and ocular studies requested by the FDA under the SPA. We will evaluate efficacy endpoints for the clinical trial at 36 months after completion of enrollment, and we anticipate conducting a planned efficacy interim analysis after a certain number of cancer events have been recorded among study patients, which we currently expect to occur by the end of the first quarter of 2008. If the efficacy results from the planned interim analysis achieve the statistical outcome specified in the SPA ( $\alpha \leq 0.001$ ), we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the efficacy interim analysis, we will continue to collect efficacy data and safety data during the review process to satisfy the FDA's safety requirements set forth in the SPA. If the efficacy results from the planned interim analysis do not satisfy the specified statistical requirements in the SPA, we plan to continue the clinical trial.

In January 2008, the DSMB reviewed safety data from approximately 1,500 patients participating in the trial and recommended to continue the Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade PIN, which we believe suggests that there are no clinically significant trends of serious side effects related to ACAPODENE®.

### OSTARINE™

In our third clinical program, Ostarine™, a SARM, is being developed for the treatment of a variety of medical conditions relating to muscle wasting and/or bone loss. Testosterone and other anabolic steroids have been proven to beneficially treat involuntary muscle wasting in acute and chronic diseases caused by aging, burns and trauma, cancer, chronic kidney disease/end-stage renal disease, chronic obstructive pulmonary disease and other similar diseases. Testosterone and other anabolic steroids, however, may cause unwanted side effects, including stimulating prostate cancer growth in men and masculinization in women. Ostarine™ is an oral nonsteroidal agent designed to have anabolic activity on muscle and bone without unwanted side effects on prostate and skin.

In November 2007, we and Merck entered into a global strategic SARM collaboration. Under this collaboration we and Merck will work together to discover, develop and commercialize current, as well as future SARM compounds.

#### *Ostarine™ for the Treatment of Cancer Cachexia*

**Scientific Overview.** Cancer cachexia is defined as the unintentional loss of lean body mass or muscle. Cancer causes the body to go into a starvation-like state that results in the preferential loss of muscle. Loss of muscle may lead to weakness, fatigue, diminished response and greater toxicity to chemotherapy, and in some cases, death. Approximately one-third of newly-diagnosed cancer patients have cancer cachexia which accounts for approximately 20% of cancer deaths. Weight loss is one of the most important indicators of how long a cancer patient will live since the survival of a patient with cancer is greatly impacted by the degree and rate of muscle wasting. A greater lean body weight may increase strength, activity levels, quality of life, response to chemotherapy and, ultimately, survival.

Testosterone increases lean body weight in both men and women. One of the causes of cancer cachexia may be reduced levels of testosterone. Testosterone therapy, however, is not used for the treatment of cancer cachexia for two reasons. First, the available delivery methods for testosterone may not be convenient for patients, and testosterone can have a number of undesirable side effects in men, such as the potential stimulation of latent prostate

cancer, aggravation of existing BPH and gynecomastia, and in women, masculinizing effects such as acne and facial hair.

We believe that Ostarine™ is similar to testosterone in activating androgen receptors in muscle, thereby promoting lean body weight, but does not stimulate sebaceous glands, the cause of hair growth and acne, or the prostate, which may exacerbate BPH or stimulate prostate cancer. In addition, Ostarine™ is being developed in an oral dosage form, which patients may find is more convenient to take.

**Potential Market.** There are approximately 1.3 million patients diagnosed with cancer each year in the United States. It has been estimated that cancer cachexia afflicts approximately 410,000 patients. Over 30 clinical trials of supplemental nutritional support alone have reported little or no benefit in counteracting cachexia in cancer patients receiving chemotherapy or radiation. There are no drugs that have been approved by the FDA for the treatment of cancer cachexia. Although there are two commercially available anabolic steroids being prescribed off-label for the treatment of cancer cachexia, chronic use of these drugs may result in liver toxicity. Also, Megace®, an appetite stimulant which has been used off-label for cancer patients, has not been shown to increase lean body mass in spite of increasing appetite.

**Clinical Trials.** We have clinical data from two Phase I clinical trials and one Phase II clinical trial of Ostarine™. In our first Phase I clinical trial, a double blind, placebo controlled, single ascending dose study in 96 healthy male volunteers, Ostarine™ was well tolerated and there were no drug-related serious adverse events. This clinical trial demonstrated that the half life of Ostarine™ was approximately 24 hours.

The second Phase I clinical trial was a double blind multiple ascending dose 14 day study to evaluate the safety, tolerability, pharmacokinetics, and specific pharmacodynamic characteristics of Ostarine™ in 48 healthy male volunteers between 18 and 45 years of age and 23 elderly males with an average age of 68 years. Measurements included routine blood chemistry and hematology, sex hormones and gonadotropins, serum prostate specific antigen, metabolic markers of bone and muscle, cutaneous sebum analysis and DEXA scanning for body composition. Overall, clinical laboratory values and hormonal effects for the 71 volunteers were consistent with anabolic activity. Comparisons of DEXA assessments from the beginning of the study to DEXA assessments after 14 days showed positive changes in body composition at clinically relevant doses; increases in lean body mass and decreases in fat mass were observed. Ostarine™ did not appear to have unwanted side effects on the prostate (serum PSA) or the skin (sebum analysis). Ostarine™ was well tolerated with no drug-related serious adverse events. However, Phase I clinical trials are not designed to show efficacy, and the results of future clinical trials may not be the same as these early observations.

In May 2006, we initiated a Phase II proof of concept, double blind, randomized, dose finding placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. The trial was designed to evaluate Ostarine™ treatment in building muscle, as well as to assess safety in both elderly men and postmenopausal women. Enrollment was completed in July 2006, and in December 2006, we reported the top line results. Without a prescribed diet or exercise regimen, all subjects treated with Ostarine™ had dose dependent increases in the primary endpoint total lean body mass. Treatment with Ostarine™ also resulted in a dose dependent improvement in functional performance, a secondary endpoint, measured by a stair climb test. Ostarine™ had a favorable safety profile, with no serious adverse events reported. Ostarine™ also exhibited tissue selectivity with beneficial effects on lean body mass and performance and with no apparent change in measurements of serum PSA, sebum production, or serum LH. We initiated a Phase II randomized, double blind, placebo controlled clinical trial evaluating Ostarine™ for the treatment of cancer cachexia in 150 patients diagnosed with non-small cell lung cancer, colorectal cancer, non-Hodgkin's lymphoma, or chronic lymphocytic leukemia. The clinical trial is being conducted at approximately 50 clinical sites in the United States, Argentina and Canada and we expect to receive data from this trial during the summer of 2008.

### ***Ostarine™ for the Treatment of Frailty or Sarcopenia***

**Scientific Overview.** Every year after age 30, people lose on average a half pound of muscle and gain a pound of fat. A typical man may lose 35% of muscle between the ages of 30 and 90 years of age. A contributing factor to muscle loss in men is that testosterone levels decrease by 1% every year after the age of 30 years. Muscle plays several important roles: muscle provides strength and endurance, supports the skeletal system, plays an important

role in metabolism, and helps protect the body by providing protein for the immune system. During an illness or trauma to the body, the energy demands of the body increase, and the body breaks down muscle to get protein to fuel the body's needs, to repair damaged organs, and to replenish immune system cells. As people lose muscle, they become fatigued more easily, making it more difficult for them to rehabilitate and recover. Loss of muscle can cause frailty, loss of independence and can worsen other conditions of aging such as osteoarthritis and osteoporosis. People who are fatigued may become more sedentary, which can lead to a reduction in their quality of life. Loss of muscle and bone with age is sometimes referred to as frailty whereas loss of bone only is referred to as osteoporosis. A 2001 study among more than 5,000 elderly adults found that over a three-year period the death rate among the frail elderly was 18%, versus a 3% mortality rate in the non-frail elderly. The frail were also far more likely to experience falls, hospitalizations and loss of independence.

We believe that Ostarine™ can build muscle and bone by improving: (1) the body's efficiency at metabolizing protein from food, (2) the body's ability to recycle protein, (3) the body's ability to burn fat and build muscle and (4) the body's ability to maintain and promote bone. We believe that Ostarine™ can increase muscle size and strength, resulting in improved function, quality of life and speed of recovery, and can prevent osteoporosis and fractures. Ostarine™ has been designed to have anabolic properties in muscle and bone without unwanted side effects, such as the stimulation of prostate cancer in men and masculinization in women. In preclinical studies of intact animals, Ostarine™ has been shown to build muscle and bone while shrinking the prostate.

**Potential Market.** There are approximately 17 million people over the age of 65 in the United States who have age related loss of muscle mass. In the United States in 2003, there were approximately 13.2 million hospital discharges among the 35 million people over the age of 65 years. It has been shown that from the time of the onset of their illness, approximately 50% of the elderly declined in health after their hospital stay. Muscle wasting is a contributing factor in their inability to completely recover. Current anabolic agents available in the market may be experiencing limited acceptance by patients due to concerns about their potential undesirable side effects, and inconvenient dosing. Testosterone is not available as an oral tablet in the United States and topical gels and patches are the most utilized forms of delivery for testosterone currently.

#### **GTx-838**

GTx-838 is another of our SARMs that is currently in preclinical development for the treatment of a variety of medical conditions relating to muscle wasting and/or bone loss. We and Merck, through our SARM collaboration, will determine the clinical development strategy of GTx-838 and other collaboration SARMs.

#### **GTx-758 for the Treatment of Advanced Prostate Cancer**

GTx-758 is an oral LH inhibitor that is currently in preclinical development for the treatment of advanced prostate cancer. In preclinical models, GTx-758 induced androgen deprivation and we believe GTx-758 can minimize certain unwanted side effects. We are planning to initiate Phase I clinical testing for GTx-758 by the end of 2008.

#### **GTx-878 for the Treatment of BPH**

GTx-878 is an estrogen receptor beta agonist that is currently in preclinical development for the treatment of BPH. In preclinical models, GTx-878 has demonstrated three activities that may be beneficial to treat BPH. We believe that GTx-878 has the potential to inhibit prostate growth, relax prostate smooth muscle tone, and reduce inflammation. We are planning to initiate Phase I clinical trials for GTx-878 in the first half of 2009.

#### **Drug Discovery and Other Research and Development**

Steroid hormone therapies, which include estrogen and testosterone therapies, have been used to treat humans for many years. Steroid hormones by their nature have unselective effects in various tissues. As a result, they have unintended side effects, which limit their clinical value.

SERM-based drugs, such as toremifene, tamoxifen and raloxifene, have achieved commercial success in

treating women as nonsteroidal small molecules that modulate hormone estrogen receptors in a tissue selective way and minimize some of the side effects of the natural estrogen hormone to treat breast cancer (toremifene and tamoxifen) or to treat postmenopausal osteoporosis (raloxifene). We believe that the previous commercial and scientific success of SERMs indicates that it is possible to design and develop classes of nonsteroidal small molecule drugs to modulate hormone receptors in addition to estrogen receptors.

We believe that our drug discovery expertise will allow us to sustain our clinical pipeline through the design and development of nonsteroidal small molecule drugs that selectively modulate hormone receptors. Our in-house medicinal chemists and scientists provide us with significant discovery and development expertise. Using our capabilities in hormone receptor biology and medicinal chemistry, we are able to target many hormone receptors and generate compounds that are designed to address the shortcomings of natural hormone therapies.

We design and synthesize new compounds based on computer, or *in silico*, models and crystal structures of a hormone receptor's binding sites. We continually modify and improve these models to reflect our study of the activity of new compounds in the laboratory, in which we determine the link between chemical structures and biological activity, or structure-activity relationships.

We also have significant medicinal scale-up and high throughput capabilities, which facilitate our rapid synthesis and evaluation of new compounds. Throughout our discovery process, we build diversity into our chemistry structures in order to improve our likelihood of success in developing novel compounds that have the potential to treat multiple indications. Through this approach, we have generated clinical product candidates for the androgen receptor such as Ostarine<sup>TM</sup>, a nuclear hormone receptor modulator. We also have conducted research and development efforts focused on other SERM and SARM compounds, other hormone receptor modulator compounds and anticancer agents.

### **Our Strategy**

Our objective is to discover, develop and commercialize small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. Key elements of our strategy to achieve this objective are to:

***Obtain Regulatory Approval of ACAPODENE<sup>®</sup>.*** We have completed our Phase III clinical trial of ACAPODENE<sup>®</sup> to treat multiple side effects of ADT, which was conducted under a SPA, and expect to file a NDA with the FDA in 2008. In addition, we are conducting our Phase III clinical trial of ACAPODENE<sup>®</sup> for the prevention of prostate cancer in high risk men with high grade PIN under a SPA from the FDA. We are focused on obtaining regulatory approval and preparing for the potential commercial launch of ACAPODENE<sup>®</sup> for these two distinct indications in men's health.

***To Commercialize ACAPODENE<sup>®</sup> in the United States and Establish Sales and Marketing Infrastructure.*** We have commercial rights to ACAPODENE<sup>®</sup> in the United States. We believe that we can effectively market ACAPODENE<sup>®</sup> to the target physician audience of urologists and medical oncologists in the United States through a specialty sales force that we plan to build.

***Partner Commercial Rights to ACAPODENE<sup>®</sup> in Europe, Asia and the Rest of the World.*** In September 2006, we licensed to Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE<sup>®</sup> and other products containing toremifene for all indications which we have licensed from Orion. We are currently pursuing a similar partnership for ACAPODENE<sup>®</sup> in Asia and other markets outside of the United States and Europe. We and Ipsen also intend to apply for market exclusivity and regulatory extensions of patent life under applicable European and U.S. laws, as appropriate, to protect our exclusive rights in ACAPODENE<sup>®</sup> for the indications that we are currently testing in clinical trials.

***Develop Diagnostic Tests for High Grade PIN.*** We are currently collaborating with several diagnostics companies, including Hybritech, Inc., a wholly owned subsidiary of Beckman Coulter, Inc., diaDexus, Inc., MacroArray Technologies, LLC, Onconome, Inc. (formerly known as Tessera, Inc.), and Gen-Probe, Incorporated to develop an accurate blood or urine test to detect high grade PIN. We will continue to seek additional

collaborations with other companies with promising high grade PIN diagnostics. We believe that men would be more willing to be tested for high grade PIN if the diagnostic test were less invasive than a prostate biopsy. In February 2007, MacroArray Technologies reported in *Clinical Cancer Research* the development of a urine test to non-invasively detect high grade PIN. Given the large number of patients with undiagnosed high grade PIN, we believe that the development of a blood or urine test would increase the detection of high grade PIN and thereby expand the already large potential market for ACAPODENE® 20 mg.

***Maintain Commercial Sales of FARESTON®.*** We intend to continue to market FARESTON® in the United States.

***Pursue Clinical Development of SARMs with Merck.*** In December 2007, we and Merck formed a global strategic collaboration for the discovery, development and commercialization of SARMs. We and Merck have pooled our programs and compounds and intend to work together to discover, develop and commercialize current, as well as future SARMs.

***Build Upon Our Other Drug Discovery Capabilities to Sustain Our Small Molecule Product Candidate Pipeline to Selectively Target Hormone Pathways.*** While our clinical development efforts to date have focused on SERM and SARM technologies, we have the capability to discover and develop additional drug candidates that target other hormone receptors. We intend to develop new molecules to treat diseases that affect large numbers of patients and are underserved by available alternatives. We have selected two new molecules, GTx-758 and GTx-878, for human clinical testing. We anticipate initiating Phase I clinical testing for GTx-758, an oral LH inhibitor for advanced prostate cancer, by the end of 2008. We anticipate initiating Phase I clinical testing for GTx-878, an estrogen receptor beta agonist for BPH, in the first half of 2009.

#### **Licenses and Collaborative Relationships**

In addition to our internally-developed and discovered small molecules, we have established and intend to continue to pursue licenses from and collaborative relationships with pharmaceutical companies and academic institutions to further the development and commercialization of our small molecule product candidates.

##### ***Merck & Co., Inc.***

On November 5, 2007, we and Merck entered into an exclusive license and collaboration agreement governing our and Merck's joint research, development and commercialization of SARM compounds and related SARM products, including SARMs currently being developed by us and Merck and those yet to be discovered, for all potential indications of interest. Our agreement with Merck became effective in December 2007.

Under the agreement, we granted to Merck an exclusive worldwide license under our SARM-related patents and know-how. We will conduct preclinical research of SARM compounds and products, and Merck will be primarily responsible for conducting and funding development and commercialization of products developed under the agreement. We received an upfront licensing fee of \$40.0 million in January 2008, and Merck has agreed to pay us \$15.0 million in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the agreement, subject to the collaboration not being terminated for cause and not occurring certain change of control events involving us during this three-year period. We are also eligible to receive under up to \$422.0 million in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine™, as defined in the agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the agreement. Merck has also agreed to pay us tiered royalties on net sales of products that may be developed under the agreement. We are responsible for any payments owed to the University of Tennessee Research Foundation, or UTRF, resulting from the collaboration with Merck. On the date the agreement became effective in December 2007, we issued Merck 1,285,347 newly-issued shares of our common stock for an aggregate purchase price of approximately \$30.0 million.

Unless terminated earlier, the collaboration agreement with Merck will remain in effect in each country of sale

at least until the expiration of all valid claims of the licensed patents in such country. However, Merck may terminate the agreement at its election at any time after a specified period of time and either party may terminate the agreement at any time for the other party's uncured material breach or bankruptcy. Under certain conditions, Merck will continue to owe royalties on certain products after it terminates the agreement without cause.

### *Ipsen Group*

In September 2006, we entered into a collaboration and license agreement with Ipsen pursuant to which we granted Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE<sup>®</sup> and other products containing toremifene in all indications that we have licensed from Orion, which include indications for all diseases or indications in humans except the treatment and prevention of breast cancer. In the agreement, both parties have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed upon period of time subsequent to the time of the first commercial launch of ACAPODENE<sup>®</sup> within the European Territory. We and Ipsen have also granted to each other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties may agree on. In accordance with the terms of the agreement, Ipsen agreed to pay us €23.0 million as a license fee and expense reimbursement, of which €1.5 million is to be paid in equal installments over a three year period from the date of the agreement. In October 2006, we received €21.5 million (approximately \$27.1 million) from Ipsen as initial payment for the license fee and expense reimbursement. In September 2007, we received €500,000 (approximately \$688,000) from Ipsen as the first annual installment payment. Pursuant to the agreement, we are also entitled to receive from Ipsen up to an aggregate of €39.0 million in milestone payments depending on the successful development and launch of ACAPODENE<sup>®</sup> in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. Ipsen has agreed to be responsible for and to pay for all clinical development, regulatory and launch activities to commercialize ACAPODENE<sup>®</sup> in the European Territory for both the high grade PIN indication and ADT indication. We will remain similarly responsible for all development and regulatory activities outside of the European Territory. However, Ipsen has agreed to pay a portion of our ACAPODENE<sup>®</sup> development costs in the United States if certain conditions are met. Under the agreement, Ipsen must elect to retain its rights to commercialize ACAPODENE<sup>®</sup> and other products containing toremifene for the high grade PIN indication. Until such time as Ipsen shall make its election, however, it is required to initiate and carry out the development of ACAPODENE<sup>®</sup> for the high grade PIN indication in the European Territory and to pay all costs associated therewith. Depending on when Ipsen exercises this election, Ipsen may be required to pay an additional license fee as well as a premium on its share of the development and clinical trial expenses incurred by us in the United States since January 1, 2006, on account of ACAPODENE<sup>®</sup> for high grade PIN. If Ipsen does not exercise its election within a certain period, Ipsen will not be obligated to pay us for a portion of the development and clinical trial expenses incurred by us in the United States since January 1, 2006, on account of ACAPODENE<sup>®</sup> for the high grade PIN indication, and we may elect to terminate Ipsen's rights to commercialize toremifene-based products for this indication, in which event all of Ipsen's rights to ACAPODENE<sup>®</sup> for the high grade PIN indication (including all associated clinical trial data and regulatory filings and approvals) will revert to us. Ipsen has agreed to pay us a royalty equal to a graduating percentage of aggregate net sales of products containing toremifene (including ACAPODENE<sup>®</sup>) in the mid-teens, which could reach the mid-twenties based on certain sales price thresholds being met, and which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. We are responsible for paying upstream royalties on ACAPODENE<sup>®</sup> to both Orion and UTRF for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

### *Orion Corporation*

In March 2000, we entered into a license and supply agreement with Orion to develop and commercialize products containing toremifene, the active pharmaceutical ingredient in FARESTON<sup>®</sup> and ACAPODENE<sup>®</sup>. Our rights under the original license agreement were limited to specific disease fields pertaining to prostate cancer. In December 2004, we entered into an agreement with Orion to purchase specified FARESTON<sup>®</sup> related assets which Orion had re-acquired from another licensee. We also entered into an amended and restated license and supply agreement with Orion which replaces the original license agreement. We paid Orion approximately \$5.2 million under the 2004 agreements for the assets and related license rights.

Under the amended and restated license and supply agreement, we obtained an exclusive license from Orion to develop and commercialize toremifene-based products, including FARESTON® and ACAPODENE®, for all human indications worldwide, except breast cancer outside of the United States. We are required to pay Orion a royalty on sales by us and our affiliates of FARESTON® for breast cancer in the United States. We are also required to pay Orion a royalty on sales by us, our affiliates and third-party sublicensees of other toremifene-based products, including ACAPODENE® if approved for commercial sale. Our license and supply agreement with Orion requires that Orion will manufacture and supply all of our and our sublicensees' needs for clinical trial and commercial grade material for toremifene-based products developed and marketed in the United States and abroad, including ACAPODENE® globally and FARESTON® in the United States. Orion may terminate its supply obligations under specified circumstances. However, we have specified rights to assume manufacture of toremifene if Orion terminates its supply of toremifene because it has ceased to manufacture toremifene, although we would have to engage another supplier to do so. The term of the amended and restated license and supply agreement lasts, on a country-by-country basis, until the later of expiration of our own patents claiming the method of use or manufacture of toremifene for prostate cancer or the end of all marketing or regulatory exclusivity which we may obtain for toremifene-based products. Orion may terminate the agreement as a result of our uncured material breach or bankruptcy.

#### ***University of Tennessee Research Foundation***

In July 2007, we and UTRF entered into a consolidated, amended and restated license agreement to consolidate and replace our two previously existing SARM license agreements with UTRF and to modify and expand certain rights and obligations of each of the parties under both license agreements. Pursuant to this agreement, we were granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University. Unless terminated earlier, the term of this agreement will continue for the longer of 20 years or until the expiration of the last valid claim of any licensed patent in the particular country in which a licensed product is being sold. UTRF may terminate the agreement for our uncured breach or upon our bankruptcy.

In September 2007, we and UTRF entered into an Amended and Restated License Agreement to replace our previously existing exclusive worldwide license agreement for ACAPODENE®. Pursuant to this agreement, we were granted exclusive worldwide rights to UTRF's method of use patents relating to SERMs, including ACAPODENE® for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee. Unless terminated earlier, the term of this agreement will continue in a particular country for the longer of 20 years from the effective date of our previously existing exclusive worldwide license agreement with UTRF for ACAPODENE® or until the expiration of the last valid claim of any licensed patent in such country. UTRF may terminate the agreement for our uncured breach or upon our bankruptcy.

Under the agreements with UTRF, we agreed to pay to UTRF a one-time, upfront fee of \$290,000 per agreement as consideration for entering into the agreements. We are also obligated to pay UTRF annual license maintenance fees and royalties on sublicense revenues and net sales of products. We also agreed to pay all expenses to file, prosecute and maintain the patents relating to the licensed SARM and SERM technologies, and are obligated to use commercially reasonable efforts to develop and commercialize products based on the licensed SARM and SERM technologies.

#### ***Ortho Biotech***

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, for andarine, one of our proprietary SARM compounds, and specified backup SARM compounds. Under the terms of the agreement, we received in April 2004 an upfront licensing fee and expense reimbursement totaling \$6.7 million. The upfront licensing fee and expense reimbursement were deferred and amortized into revenue on a straight-line basis over the estimated five year andarine development period. In December 2006, we reacquired full rights to develop and commercialize andarine and all backup compounds



previously licensed to Ortho Biotech, and the joint collaboration and license agreement was terminated by mutual agreement of the parties. In connection with the termination of the Ortho Biotech agreement, we recognized the associated \$3.1 million balance of deferred revenue as additional collaboration revenue.

### **Manufacturing**

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of FARESTON<sup>®</sup>, ACAPODENE<sup>®</sup> or any of our SARMS. We currently rely and expect to continue to rely on third parties for the manufacture of our product candidates or products that we may develop.

We have agreed to purchase from Orion our worldwide requirements for toremifene citrate, the active pharmaceutical ingredient in ACAPODENE<sup>®</sup> and FARESTON<sup>®</sup> under an exclusive license and supply agreement providing for Orion to supply our requirements for clinical and commercial product. Orion has agreed to supply us with, and we have agreed to purchase from Orion, our worldwide requirements of toremifene citrate in specified doses in finished tablet form at specified transfer prices. Similarly, Ipsen has agreed to purchase from Orion, ACAPODENE<sup>®</sup> tablets for clinical testing and commercial sale in the European Territory under an amended supply agreement with Orion. As such, both we and Ipsen rely on Orion as the single source supplier of ACAPODENE<sup>®</sup>. Orion's manufacturing facility also produces commercial quantities of toremifene tablets for FARESTON<sup>®</sup> and complies with the FDA's current Good Manufacturing Practice regulations. The raw materials necessary to manufacture toremifene citrate tablets are readily available, but Orion is our only supplier of toremifene tablets. Our license and supply agreement with Orion does not provide us with the current right to manufacture toremifene. In addition, under the terms of our agreement with Orion, we have agreed to purchase our requirements for toremifene tablets from Orion during the term of the agreement, which extends for the life of our patent rights, beyond the term of Orion's patents with respect to the composition of matter of toremifene.

Orion may terminate its obligation to supply us and Ipsen with toremifene if Orion permanently ceases the manufacture of toremifene subject to giving us and Ipsen proper notice or Orion may terminate its obligation to supply us with toremifene if marketing approval for ACAPODENE<sup>®</sup> for use in any of the licensed fields, except breast cancer, is not granted in the United States prior to December 31, 2009. There are a number of circumstances in which Orion is required to grant manufacturing rights to us and Ipsen, including following termination of its supply obligation as set forth above, failure by Orion to supply product to us for 90 days or to supply product in dosages or formulations other than the dosages and formulations specified in the agreement or termination of the agreement by us following a breach by Orion. Also, under certain circumstances, if additional manufacturing capacity is needed to supply our increasing need for product, we have the right at certain sales levels to require Orion to qualify an additional manufacturing site at our expense. Under these circumstances, we and Ipsen would need to make arrangements for an alternative supply which would still have to be made with a qualified alternative supplier with the appropriate FDA approval in order for us to obtain our supply requirements for ACAPODENE<sup>®</sup>. However, in the event that Orion terminates the license agreement as a result of our bankruptcy or a material breach of the agreement by us that is not cured, we would not have the right to manufacture toremifene for ACAPODENE<sup>®</sup> until Orion's patents with respect to the composition of matter of toremifene expire in the United States. Although Orion's composition of matter patents within the European Territory have expired, and as such, would not prevent Ipsen from manufacturing ACAPODENE<sup>®</sup> within the European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to Ipsen or to assist Ipsen in developing manufacturing capabilities to meet Ipsen's supply needs if Ipsen is in material breach of its supply agreement with Orion. We and Ipsen have agreed to collaborate with each other in the event either of our supply rights are terminated by Orion for any reason.

There are no complicated chemistries or unusual equipment required in the manufacturing process for our SARMS. The active ingredient in Ostarine<sup>™</sup> and our other SARMS is manufactured using a four-step synthetic process that uses commercially available starting materials and raw materials for each step. We have contracted with third party vendors for the manufacture of Ostarine<sup>™</sup> drug substance and the supply of Ostarine<sup>™</sup> drug product for our Phase II clinical trial for the treatment of muscle wasting in cancer patients, known as cancer cachexia. However, Merck has assumed primary manufacturing responsibility for Ostarine<sup>™</sup> and other SARM products developed under our license and collaboration agreement with Merck.

## Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize similar products that are safer, more effective, have fewer side effects or are less expensive than any products that we and/or our collaborators may develop. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

### ***ACAPODENE® 20 mg for the Prevention of Prostate Cancer in High Risk Men with High Grade PIN***

Currently, there are no drug products that would compete with ACAPODENE® 20 mg for the treatment of high grade PIN to reduce the incidence of prostate cancer. There are government sponsored studies looking at the ability of nutritional supplements to prevent prostate cancer in men with high grade PIN. These studies are much smaller than the ACAPODENE® 20 mg Phase III trial and may not have enough clinical patients to show a statistically significant benefit. Avodart® (dutasteride), from GlaxoSmithKline, is being evaluated in a Phase III clinical trial in prostate cancer prevention in men with elevated PSA, but men with high grade PIN were excluded from the Avodart trial.

### ***ACAPODENE® 80 mg for the Treatment of Multiple Serious Side Effects of ADT***

Currently, there are no products that have been approved by the FDA to treat multiple serious side effects of ADT. We are aware of a number of drugs that are marketed or prescribed off-label for the treatment of single side effects. For example, Evista® (raloxifene hydrochloride), a SERM marketed by Eli Lilly, Fosamax® (alendronate sodium), a bisphosphonate marketed by Merck, Zometa® (zoledronic acid) a bisphosphonate marketed by Novartis, and Actonel® (risendronate sodium), a bisphosphonate marketed by Sanofi-Aventis and Procter & Gamble, are each prescribed for the treatment of osteoporosis. Amgen has an investigational drug, denosumab, in Phase III clinical trials for the treatment of osteoporosis in men undergoing ADT. Effexor® (venlafaxine hydrochloride), marketed by Wyeth Pharmaceuticals, Catapres® (clonidine hydrochloride), marketed by Boehringer Ingelheim, and Megace® (megestrol acetate), marketed by Bristol Myers Squibb, are prescribed off-label to treat hot flashes caused by ADT. External beam radiation and tamoxifen are both used to treat gynecomastia. There can be significant side effects associated with the use of these drugs and radiation treatment. Most patients would need to take several different drugs and potentially receive radiation treatments to treat multiple serious side effects of ADT. In contrast, we believe that ACAPODENE® 80 mg as a single product candidate has the potential to treat multiple serious side effects.

### ***SARMs for the Treatment of Cancer Cachexia and Frailty, or Sarcopenia***

There are currently no drugs that have been approved by the FDA for the treatment of cancer cachexia. Although there are two commercially available drugs, nandrolone and oxandrolone, that are being prescribed off-label for the treatment of some types of cancer cachexia, chronic use of these drugs may result in bleeding liver cysts and liver cell tumors. Nandrolone is an oral steroid that is available from Steris Laboratories, a subsidiary of Watson Pharmaceuticals. Oxandrin® (oxandrolone) is indicated as an adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections and severe trauma and in some patients who without pathophysiologic reasons fail to maintain normal weight but has also been prescribed off-label for cancer cachexia. Oxandrin® was marketed by Savient Pharmaceuticals and generated approximately \$60 million in annual sales. Savient has discontinued production of Oxandrin® following the introduction of an authorized generic. Oxandrin® has a black box warning for liver toxicity and has warnings and precautions related to increasing the risk

for prostate cancer and virilization in women.

Testosterone products have been used off-label to treat andropause and muscle wasting. Owing to its potentially unwanted effects in the prostate, and possible inconvenient dosing, we believe that testosterone products have had a limited impact on the market for muscle wasting. TAP Pharmaceuticals and Ligand Pharmaceuticals have announced a collaboration to develop a SARM and have been conducting Phase I clinical studies. Other pharmaceutical companies are also developing SARMS. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine™. Megace® (megesterol acetate) and Marinol® (dronasinol) are appetite stimulants approved for AIDS patients which are used off-label for cancer cachexia. Neither Megace® nor Marinol® increase muscle and neither have been shown to improve physical function.

### ***FARESTON® for the Treatment of Breast Cancer***

There are a number of drugs that have been approved by the FDA for the treatment of breast cancer. Tamoxifen, which is marketed by AstraZeneca and several generic manufacturers, has been approved by the FDA for the treatment of advanced breast cancer and the reduction of breast cancer in women at high risk for developing the disease. The aromatase inhibitors, or AIs, such as anastrozole, letrozole and exemestane, are used to treat breast cancer in postmenopausal women. The AIs are growing at the expense of SERMs due to clinical trials such as the clinical trial entitled "Arimidex and Tamoxifen: Alone or in Combination" which has shown efficacy and tolerability advantages for AIs compared to tamoxifen.

### **Sales and Marketing**

In order to commercialize any future products, we must broaden our sales and marketing infrastructure or collaborate with third parties with sales and marketing experience and personnel. We plan to build a small, highly-focused, specialty sales and marketing infrastructure, which we expect to include 50 to 100 sales representatives, to market ACAPODENE® to the relatively small and concentrated community of urologists and medical oncologists in the United States and to market FARESTON® to targeted prescribers, principally medical oncologists and other key specialists targeted in the United States. We believe that the urology and medical oncology markets in the United States are readily accessible by a limited sales and marketing presence due to the concentration of prescribing physicians. We have partnered with Ipsen to commercialize ACAPODENE® in Europe. We are currently seeking partners to market ACAPODENE® in Asia and other markets outside of the United States and Europe.

If Ostarine™ or another of the SARMS under development by us and Merck is approved by the FDA, Merck will commercialize the drug and we will have the opportunity to participate in commercialization through medical affairs and potentially also through copromotion.

### **Intellectual Property**

We will be able to protect our technology from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are an essential element of our business.

For ACAPODENE® in the United States and internationally, we have entered into an amended and restated license and supply agreement with Orion Corporation granting us an exclusive license under Orion's patents covering the composition of matter of toremifene, the active pharmaceutical ingredient in ACAPODENE®, for all uses in humans in the United States, and for all human uses outside the United States other than to treat breast cancer. The patent for toremifene will expire in the United States in 2009 and will expire in Australia, Italy, Sweden and Switzerland in 2008. This patent has already expired in other European countries and in Japan and is likely to expire in countries outside the United States before we commercialize ACAPODENE®. As a result, outside of the United States and in the United States after 2009, we will need to rely primarily on the protection afforded by the method of use patents that either have been already issued or other patents that may later be issued in respect of our owned and/or licensed patent applications relating to the use of ACAPODENE® for the relevant indications we seek.

We have licensed from UTRF method of use patents for specific disease indications and doses in the United States and issued and pending patent applications internationally related to the use of ACAPODENE® 20 mg for the reduction in the incidence of prostate cancer in high risk men with high grade PIN. The method of use patents issued in the United States related to the use of ACAPODENE® for this indication will begin expiring in 2019.

We have our own pending method of use patent applications in the United States and internationally related to the use of ACAPODENE® 80 mg for the treatment of osteoporosis, gynecomastia and hot flashes as multiple serious side effects of ADT in men with prostate cancer. A method of use patent related to the use of ACAPODENE® for the treatment of ADT-induced osteoporosis and bone fractures in men with prostate cancer is issued in the United States and will expire in 2023.

In all countries in which we hold or have licensed rights to patents or patent applications related to ACAPODENE®, the composition of matter patents for toremifene, the active pharmaceutical ingredient of ACAPODENE®, will expire before the method of use patents. Furthermore, with respect to the method of use of ACAPODENE® 80 mg for the treatment of osteoporosis, hot flashes and gynecomastia as multiple serious side effects of ADT in men with prostate cancer worldwide and the method of use of ACAPODENE® 20 mg for the reduction in the incidence of prostate cancer in high risk men with high grade PIN outside the United States, we have some patents issued and many more pending patent applications. Method of use patents for compounds where the composition of matter patents have expired carry the risk of individual physician prescribed off-label use of the subject compounds.

In the event that patents issued in respect of our pending method of use patent applications, after the expiration of the patent covering the composition of matter of toremifene in a particular country, competitors could market and sell generic versions of toremifene at doses and in formulations that are bioequivalent to FARESTON® (toremifene citrate 60 mg) for uses other than the indications for ACAPODENE® covered by these pending method of use patent applications, and individual physicians would be permitted to prescribe generic versions of toremifene for indications that are protected by our or our licensors' method of use patents and pending patent applications. Assuming ACAPODENE® receives appropriate marketing approval, after the expiration of the patent covering the composition of matter of toremifene in a particular country, if patents do not issue in respect of our pending method of use patent applications related to the use of ACAPODENE® 80 mg for the treatment of osteoporosis, hot flashes and gynecomastia as multiple serious side effects of ADT in men with prostate cancer worldwide and the method of use of ACAPODENE® 20 mg for the reduction in the incidence of prostate cancer in high risk men with high grade PIN outside the United States, competitors could market and sell generic versions of toremifene at doses and in formulations that are bioequivalent to FARESTON® (toremifene citrate 60 mg) tablets for these indications.

Until January 2005, our license from Orion was limited to the use of toremifene for the prevention and treatment of prostate cancer and the prevention and treatment of osteoporosis, hot flashes and gynecomastia as multiple serious side effects of ADT in the treatment of prostate cancer. We have since acquired the rights from Orion to market, sell and distribute a 60 mg toremifene tablet under the trademark FARESTON® for the treatment of advanced breast cancer in the United States and the rights to market, sell and distribute toremifene for all other indications in humans in the United States and in the rest of world except for breast cancer outside of the United States.

For Ostarine™ and our other SARMS, including GTx-838, we have an exclusive license from the UTRF under its issued patents and pending patent applications in the United States and internationally covering the composition of matter of the active pharmaceutical ingredient in these product indications, pharmaceutical compositions and formulations and methods of synthesizing the active pharmaceutical ingredients. We also have licensed pending patent applications in the United States and internationally related to methods for building muscle mass and bone in patients and treating frailty, osteoporosis, cancer cachexia and other wasting diseases using Ostarine™ and other SARMS. As part of our collaboration with Merck, we have granted an exclusive license to Merck for these issued patents and pending patent applications that we have licensed from UTRF.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and confidentiality agreements and our employees to execute assignment of invention agreements to the Company on commencement

of their employment. Agreements with our employees also prevent them from bringing any proprietary rights of third parties to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

## **Government Regulation**

### ***New Drug Development and Approval Process***

Numerous governmental authorities in the United States and other countries extensively regulate the testing, clinical development, manufacturing and marketing of pharmaceutical products and ongoing research and development activities. In the United States, the FDA rigorously reviews pharmaceutical products under the Federal Food, Drug, and Cosmetic Act and applicable regulations. Non-compliance with FDA regulations can result in administrative and judicial sanctions, including warning letters, clinical holds, fines, recall or seizure of products, injunctions, total or partial suspension of production, refusal of the government to approve marketing applications or allow entry into supply contracts, refusal to permit import or export of products, civil penalties, criminal prosecution and other actions affecting a company and its products. The FDA also has the authority to revoke previously granted marketing authorizations.

To secure FDA approval, an applicant must submit extensive preclinical and clinical data, as well as information about product manufacturing processes and facilities and other supporting information to the FDA for each indication to establish a product candidate's safety and efficacy. The development and approval process takes many years, requires the expenditure of substantial resources and may be subject to delays or limitations of approval or rejection of an applicant's new drug application. Even if the FDA approves a product, the approval is subject to post-marketing surveillance, adverse drug experience and other recordkeeping and reporting obligations, and may involve ongoing requirements for post-marketing studies. The FDA also recently obtained authority to place conditions on any approvals that could restrict the commercial applications, advertising, promotion or distribution of these products. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

### ***Preclinical and Clinical Testing***

Preclinical studies involve laboratory evaluation of product characteristics and animal studies to assess the biological activity and safety of the product. In some cases, long-term preclinical studies are conducted while clinical studies are ongoing. The FDA, under its Good Laboratory Practices regulations, regulates preclinical studies. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring these studies to be replicated. When the preclinical testing is considered adequate by the sponsor to demonstrate the safety and scientific rationale for initial human studies, the results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an Investigational New Drug application, or IND. The IND becomes effective, if not rejected by the FDA, within 30 days after the FDA receives the IND. The FDA may, either during the 30-day period after filing of an IND or at any future time, impose a clinical hold on proposed or ongoing clinical trials on various grounds, including that the study subjects are or would be exposed to an unreasonable and significant health risk. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the investigational product candidates to humans under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with Good Clinical Practices under protocols submitted to the FDA as part of the IND. In addition, each clinical trial must be approved and conducted under the auspices of an Investigational Review Board, or IRB, and with patient informed consent. The IRB typically considers, among other things, ethical factors and the safety of human subjects.

Clinical trials are conducted in three sequential phases, but the phases may overlap. Phase I clinical trials usually involve healthy human subjects. The goal of a Phase I clinical trial is to establish initial data about the safety, tolerability and pharmacokinetic properties of the product candidates in humans. In Phase II clinical trials, controlled studies are conducted on an expanded population of patients with the targeted disease. The primary purpose of these tests is to evaluate the effectiveness of the drug candidate on the patients to determine if there are

any side effects or other risks associated with the drug and to determine the optimal dose of the drug from the safety and efficacy profile developed from the clinical study. Phase III trials involve even larger patient populations, often with several hundred or even several thousand patients, depending on the use for which the drug is being studied. Phase III trials are intended to establish the overall risk-benefit ratio of the drug and provide, if appropriate, an adequate basis for product labeling. During all clinical trials, physicians monitor the patients to determine effectiveness and to observe and report any reactions or other safety risks that may result from use of the drug candidate.

### ***Product Formulation and Manufacture***

Concurrent with clinical trials and preclinical studies, companies must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product. In addition, manufacturers, including contract manufacturers, are required to comply with current applicable FDA Good Manufacturing Practice regulations. The current Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. The manufacturing process must be capable of consistently producing quality batches of the product and the manufacturer must develop methods for testing the quality, purity and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and chemistry stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

Compliance with current Good Manufacturing Practice regulations also is a condition of new drug application approval. The FDA must approve manufacturing facilities before they can be used in the commercial manufacture of drug products. In addition, manufacturing establishments are subject to pre-approval inspections and unannounced periodic inspections.

### ***New Drug Application Process***

After the completion of the clinical trial phases of development, if the sponsor concludes that there is substantial evidence that the drug candidate is safe and effective for its intended use, the sponsor may submit a NDA to the FDA. The application must contain all of the information on the drug candidate gathered to that date, including data from the clinical trials, and be accompanied by a user fee.

Under the Prescription Drug User Fee Act, or PDUFA, submission of a NDA with clinical data requires payment of a fee, with some exceptions. In return, the FDA assigns a goal of six or ten months from filing of the application to return of a first "complete response," in which the FDA may approve the product or request additional information. There can be no assurance that an application will be approved within the performance goal timeframe established under PDUFA. The FDA initially determines whether a NDA as submitted is acceptable for filing. The FDA may refuse to file an application, in which case the FDA retains one-half of the user fees. If the submission is accepted for filing, the FDA begins an in-depth review of the application. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. The FDA is not bound by the recommendation of an advisory committee.

If the FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue an approval letter authorizing commercial marketing of the drug candidate for specified indications. The FDA could also issue an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. On the other hand, if the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a non-approvable letter.

### ***Marketing Approval and Post-Marketing Obligations***

If the FDA approves an application, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may require post-marketing studies, also known as Phase IV studies, as a condition of approval. In addition to studies required by the FDA after approval, trials and studies are often conducted to explore new indications for the drug. The purpose of these trials and studies and related publications is to develop data to support additional indications for the drug,

which must be approved by the FDA, and to increase its acceptance in the medical community. In addition, some post-marketing studies are done at the request of the FDA to develop additional information regarding the safety of a product.

In accordance with newly-gained authority pursuant to the Food and Drug Administration Amendments Act of 2007, the FDA may impose risk evaluation mitigation strategies, or REMs, on a product if the FDA believes there is a reason to monitor the safety of the drug in the marketplace. REMs are a new tool for the FDA, and it is unclear how the agency will implement this enforcement authority. However, REMs could add training requirements for healthcare professionals, safety communications efforts, and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMs activities and adjust them if need be. The financial impact of REMs are uncertain at this time.

Any products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including record keeping requirements, reporting of adverse experiences with the drug, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their establishments and are subject to periodic unannounced inspections for compliance with Good Manufacturing Practice requirements. Also, newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, or even in some instances revocation or withdrawal of the product's approval.

#### ***Drug Price Competition and Patent Term Restoration Act of 1984***

Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, a portion of a product's patent term that was lost during clinical development and application review by the FDA may be restored. The Hatch-Waxman Act also provides for a statutory protection, known as exclusivity, against the FDA's acceptance or approval of certain competitor applications. The Hatch-Waxman Act also provides the legal basis for the approval of abbreviated new drug applications, or ANDAs.

Patent term extension can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an IND and the submission date of a NDA, plus the time between the submission date of a NDA and the approval of that application. Patent term extensions, however, are subject to a maximum extension of five years, and the patent term extension cannot extend the remaining term of a patent beyond a total of 14 years. The application for patent term extension is subject to approval by the United States Patent and Trademark Office in conjunction with the FDA. It generally takes at least six months to obtain approval of the application for patent term extension.

The Hatch-Waxman Act also provides for a period of statutory protection for new drugs that receive NDA approval from the FDA. If a new drug receives NDA approval as a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active entity, then the Hatch-Waxman Act prohibits an ANDA or a NDA submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetics Act, where the applicant does not own or have a legal right of reference to all of the data required for approval to be submitted by another company for a generic version of such drug (505(b)(2) NDA), with some exceptions, for a period of five years from the date of approval of the NDA. The statutory protection provided pursuant to the Hatch-Waxman Act will not prevent the filing or approval of a full NDA, as opposed to an ANDA or 505(b)(2) NDA, for any drug, including, for example, a drug with the same active ingredient, dosage form, route of administration, strength and conditions of use. In order to obtain a NDA, however, a competitor would be required to conduct its own clinical trials.

If NDA approval is received for a new drug containing an active ingredient that was previously approved by the FDA but the NDA is for a drug that includes an innovation over the previously approved drug, for example, a NDA approval for a new indication or formulation of the drug with the same active ingredient, and if such NDA approval was dependent upon the submission to the FDA of new clinical investigations, other than bioavailability studies, then the Hatch-Waxman Act prohibits the FDA from making effective the approval of an ANDA or 505(b)(2) NDA

for a generic version of such drug for a period of three years from the date of the NDA approval. This three year exclusivity, however, only covers the innovation associated with the NDA to which it attaches. Thus, the three year exclusivity does not prohibit the FDA, with limited exceptions, from approving ANDAs or 505(b)(2) NDAs for drugs containing the same active ingredient but without the new innovation.

While the Hatch-Waxman Act provides certain patent restoration and exclusivity protections to innovator drug manufacturers, it also permits the FDA to approve ANDAs for generic versions of their drugs. The ANDA process permits competitor companies to obtain marketing approval for a drug with the same active ingredient for the same uses but does not require the conduct and submission of clinical studies demonstrating safety and effectiveness for that product. Instead of safety and effectiveness data, an ANDA applicant needs only to submit data demonstrating that its product is bioequivalent to the innovator product as well as relevant chemistry, manufacturing and product data. The Hatch-Waxman Act also instituted a third type of drug application that requires the same information as a NDA, including full reports of clinical and preclinical studies, except that some of the information from the reports required for marketing approval comes from studies which the applicant does not own or have a legal right of reference. This type of application, a 505(b)(2) NDA, permits a manufacturer to obtain marketing approval for a drug without needing to conduct or obtain a right of reference for all of the required studies.

Finally, the Hatch-Waxman Act requires, in some circumstances, an applicant submitting an ANDA or 505(b)(2) NDA to notify the patent owner and the holder of the approved NDA of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed. Upon receipt of this notice, the patent owner and the NDA holder have 45 days to bring a patent infringement suit in federal district court and obtain a 30-month stay against the company seeking to reference the NDA. The NDA holder could still file a patent suit after the 45 days, but if they miss the 45-day deadline, they would not have the benefit of the 30-month stay. Alternatively, after this 45-day period, the applicant may file a declaratory judgment action, seeking a determination that the patent is invalid or will not be infringed. Depending on the circumstances, however, the applicant may not be able to demonstrate a controversy sufficient to confer jurisdiction on the court. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the Hatch-Waxman Act provides a 30-month stay on the approval of the competitor's ANDA or 505(b)(2) NDA. If the litigation is resolved in favor of the competitor or the challenged patent expires during the 30-month period, unless otherwise extended by court order, the stay is lifted and the FDA may approve the application. Under regulations recently issued by the FDA, and essentially codified under the recent Medicare prescription drug legislation, the patent owner and the NDA holder have the opportunity to trigger only a single 30-month stay per ANDA or 505(b)(2) NDA. Once the applicant of the ANDA or 505(b)(2) NDA has notified the patent owner and the NDA holder of the infringement, the applicant cannot be subjected to another 30-month stay, even if the applicant becomes aware of additional patents that may be infringed by its product.

### ***Pharmaceutical Pricing and Reimbursement***

In both domestic and foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare product candidates. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. Adoption of new legislation could further limit reimbursement for pharmaceuticals.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has and will continue to increase the pressure on pharmaceutical pricing. Currently, our only marketed product, FARESTON® for the treatment of metastatic breast cancer, is eligible for coverage and reimbursement by third-party payors.



## Research and Development

Since our inception, we have been focused on drug discovery, preclinical development and clinical development programs. Our research and development expenses were \$38.5 million for the year ended December 31, 2007, \$33.9 million for the year ended December 31, 2006 and \$30.9 million for the year ended December 31, 2005.

## Employees

As of December 31, 2007, we had 111 employees, 30 of whom were M.D.s and/or Ph.D.s. None of our employees is subject to a collective bargaining agreement. We believe that we have good relations with our employees.

## Available Information

We file reports with the Securities and Exchange Commission, or SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q, and other reports from time to time. The public may read and copy any materials filed with the SEC at the SEC's Public Reference Room at 100 F Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We are an electronic filer and the SEC maintains an Internet site at <http://www.sec.gov> that contains the reports, proxy and information statements, and other information filed electronically. Our website address is <http://www.gtxinc.com>. Please note that these website addresses are provided as inactive textual references only. We make available free of charge through our website our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The information provided on our website is not part of this report, and is therefore not incorporated by reference unless such information is otherwise specifically referenced elsewhere in this report.

## Executive Officers of the Registrant

The following table sets forth information about our executive officers as of February 29, 2008.

Name	Age	Position(s)
Mitchell S. Steiner, M.D., F.A.C.S.....	47	Chief Executive Officer and Vice Chairman of the Board of Directors
Marc S. Hanover.....	45	President, Chief Operating Officer and Director
Ronald A. Morton, Jr., M.D., F.A.C.S.....	49	Vice President, Chief Medical Officer
Henry P. Doggrell.....	59	Vice President, General Counsel and Secretary
Mark E. Mosteller.....	45	Vice President, Chief Financial Officer and Treasurer
K. Gary Barnette, Ph.D.....	40	Vice President, Clinical Research and Development Strategy
James T. Dalton, Ph.D.....	45	Vice President, Preclinical Research and Development
Gregory A. Deener.....	46	Vice President, Sales and Marketing, Product Commercialization
Jeffrey G. Hesselberg .....	49	Vice President, Regulatory Affairs
Christopher K. West .....	41	Vice President, Sales

*Mitchell S. Steiner, M.D., F.A.C.S.*, a co-founder of GTx, has served as our Chief Executive Officer and Vice Chairman of our Board of Directors since our inception in September 1997. From 1995 to 2003, Dr. Steiner held numerous academic appointments, including Chairman and Professor of Urology, Director of Urologic Oncology and Research and the Chair of Excellence in Urologic Oncology at the University of Tennessee. Since 2003, Dr.

Steiner has continued to serve on the faculty at the University of Tennessee. Dr. Steiner holds a B.A. in Molecular Biology from Vanderbilt University and an M.D. from the University of Tennessee, and performed his surgery and urologic training at The Johns Hopkins Hospital.

**Marc S. Hanover**, a co-founder of GTx, has served as our President and Chief Operating Officer and a director since our inception in September 1997. Prior to joining GTx, Mr. Hanover was a founder of Equity Partners International, Inc., a private equity firm in Memphis, Tennessee, and participated as a founder and investor in three healthcare companies. From 1985 to 1997, Mr. Hanover was a Senior Vice President and a member of the Executive Management Committee of National Bank of Commerce in Memphis, Tennessee. Mr. Hanover holds a B.S. in Biology from the University of Memphis and a MBA in Finance from the University of Memphis.

**Ronald A. Morton, Jr., M.D., F.A.C.S.**, was appointed Vice President and Chief Medical Officer in April 2007. He joined GTx from the University of Medicine & Dentistry of New Jersey Robert Wood Johnson Medical School, where he served as Professor of Surgery, Chief of Urology and Director of Urologic Oncology for the Cancer Institute of New Jersey from January 2004 until April 2007. Dr. Morton also held the Conzen Chair for Clinical Research and was the Director of the New Jersey Center for Clinical and Translational Sciences. Prior to joining Robert Wood Johnson Medical School in 2004, Dr. Morton held a dual faculty appointment at the Baylor College of Medicine in the Scott Department of Urology and in the Department of Molecular and Cell Biology (May 1994 to December 2003), was Clinical Director of the Baylor Adult Urology Program (July 2000 to December 2003), Chief of Urology at the Houston Veterans Administration Medical Center (January 1999 to December 2003), and Director of the Baylor Prostate Cancer Center Research Laboratories (July 1996 to December 2003). He received his bachelor and medical degrees from the Johns Hopkins University and completed his urology training and postdoctoral fellowship and was an AFUD Scholar at the Johns Hopkins Brady Urological Institute.

**Henry P. Doggrell** has served as our General Counsel and Secretary since October 2001 and was appointed Vice President on January 20, 2005. From April 1998 to August 2001, Mr. Doggrell was Senior Vice President, Corporate Affairs at Buckeye Technologies, Inc., a specialty cellulose company, where he was responsible for matters including corporate finance, investor relations, mergers and acquisitions, intellectual property and licensing and strategic development. From 1996 to 1998, Mr. Doggrell served as General Counsel and Secretary of Buckeye Technologies. Prior to joining Buckeye Technologies, Mr. Doggrell was a partner of the Baker, Donelson, Bearman, Caldwell and Berkowitz law firm from 1988 to 1996, where he served as a member of the law firm management committee and Chair of the firm's Corporate Securities department. Mr. Doggrell holds a B.S. in Commerce from the University of Virginia and a JD from Vanderbilt University.

**Mark E. Mosteller** has served as our Chief Financial Officer since August 2001 and was appointed Vice President and Treasurer on January 20, 2005. From April 1997 to August 2001, Mr. Mosteller was an Executive Vice President of Union Planters Bank National Association, a subsidiary of Union Planters Corporation, a bank holding company, and Chief Operating Officer of Union Planters Mortgage, the mortgage division of Union Planters Bank National Association. From 1994 to 1997, Mr. Mosteller was the Chief Financial Officer of Boatmen's National Mortgage, Inc., the mortgage subsidiary of Boatmen's Bancshares, Inc. From 1984 to 1994, Mr. Mosteller was employed as an audit senior manager with Ernst & Young LLP. Mr. Mosteller is a Certified Public Accountant and holds a B.S. in Accounting from the University of Tennessee.

**K. Gary Barnette, Ph.D.**, was appointed Vice President, Clinical Research and Development Strategy in November 2005, and prior to that he served as Vice President, Clinical Research and Development since January 20, 2005. He also served as our Director of Regulatory Affairs from December 2001 until April 2007. From May 1998 to December 2001, Dr. Barnette was Assistant Director and then Director, Regulatory Affairs at Solvay Pharmaceuticals, Inc., a specialty pharmaceutical company. From March 1995 to May 1998, Dr. Barnette was a Clinical Pharmacology and Biopharmaceutics Reviewer at the FDA, where he reviewed in the Divisions of Reproductive and Urologic Drug Products, Metabolic and Endocrine Drug Products and Gastrointestinal and Coagulation Drug Products. Dr. Barnette holds a B.S. in Biology from Salem College, and a Ph.D. in Basic Pharmaceutical Sciences from West Virginia University.

**James T. Dalton, Ph.D.**, has served as Vice President, Preclinical Research and Development since January 2005. Dr. Dalton served as a scientific consultant to GTx from 1999 to 2005. Prior to joining GTx, Dr. Dalton held several academic appointments including Assistant and Associate Professor of Pharmaceutical Sciences in the

College of Pharmacy at the University of Tennessee, Memphis (1992-2000) and Professor in the Division of Pharmaceutics, College of Pharmacy at The Ohio State University (2000-2007). SARMs were first discovered in Dr. Dalton's research laboratories, and he is co-inventor on all SARM patents. Dr. Dalton holds a B.S. in Pharmacy from the University of Cincinnati and a Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University.

**Gregory A. Deener** was appointed Vice President, Sales and Marketing, Product Commercialization on January 20, 2005, and prior to that he served as our Director of Marketing and Sales since February 2004. Mr. Deener has over 20 years of experience in Marketing and Sales and has launched a urology medicine within the U.S. From 1996 to December 2003, Mr. Deener served as a Marketing Director for GlaxoSmithKline in various roles within the U.S. and Europe. Most recently Mr. Deener was responsible for the launch of Avodart, a urology medicine for BPH. From 1983 to 1996, Mr. Deener worked for Procter & Gamble in Brand Management and Sales. Mr. Deener holds a B.S. in Business Administration from the University of North Carolina at Chapel Hill.

**Jeffrey G. Hesselberg** was appointed Vice President, Regulatory Affairs in April 2007, and has over 19 years of experience in the biopharmaceutical industry, including 13 years of regulatory affairs drug development experience. From 1996 to April 2007, Mr. Hesselberg served as Manager, Associate Director, and then Director of Regulatory Affairs for ICOS Corporation. Most recently, Mr. Hesselberg worked on the successful development, launch and commercialization of Cialis<sup>®</sup> (tadalafil) for the treatment of erectile dysfunction. From 1984 to 1996, Mr. Hesselberg worked for Immunex Corporation and the Puget Sound Blood Center. Mr. Hesselberg holds a B.S. in Molecular Biology from the University of Wisconsin-Madison and a MBA from the University of Washington.

**Christopher K. West** was appointed Vice President, Sales on January 7, 2008. Mr. West has over 14 years of pharmaceuticals sales and marketing experience and joins us from Warner Chilcott, Limited where he served as Regional Sales Director (2006) and then as head of Sales and Marketing for the Dermatology division (2007). From 2002 through 2006, Mr. West worked for GlaxoSmithKline plc in marketing positions of increasing responsibility for the urology medicines Avodart<sup>®</sup>, Valtrex<sup>®</sup> and Advair<sup>®</sup>. From 1992 to 2000, Mr. West worked for Warner Lambert's Parke-Davis division in a variety of sales, sales training, and sales management positions. Mr. West is a graduate of the United States Military Academy at West Point and the Fuqua School of Business at Duke University.

## **ITEM 1A. RISK FACTORS**

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. Our business faces significant risks and the risks described below may not be the only risks we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. If any of these risks occur, our business, results of operations or financial condition could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

### **Risks Related to Our Financial Results and Need for Additional Financing**

*We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.*

We have a limited operating history. As of December 31, 2007, we had an accumulated deficit of \$270.1 million, of which \$96.3 million related to non-cash dividends and adjustments to the preferred stock redemption value. We have incurred losses in each year since our inception in 1997. Net losses were \$40.4 million for the year ended December 31, 2007, \$35.5 million in 2006, and \$36.8 million in 2005. We expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with developing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have primarily financed

our operations and internal growth through sales of common stock and preferred stock, including \$30.0 million in proceeds from the sale of our common stock to Merck & Co., Inc., or Merck, pursuant to a stock purchase agreement we entered into with Merck in November 2007. In addition, we have received upfront license fees and payments pursuant to our collaborative arrangements with third parties, including \$40.0 million in upfront license fees from Merck received in January 2008. FARESTON<sup>®</sup> is currently our only commercial product and, we expect, will account for all of our product revenue for the foreseeable future. For the year ended December 31, 2007, we recognized \$1.1 million in net revenues from the sale of FARESTON<sup>®</sup>.

We expect our research and development expenses to increase in connection with our ongoing clinical trials. In addition, subject to regulatory approval of any of our product candidates, we expect to incur additional sales and marketing expenses and increased manufacturing expenses.

***We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.***

We will need to raise additional capital to:

- fund our operations and clinical trials;
- continue our research and development; and
- commercialize our product candidates, if any such product candidates receive regulatory approval for commercial sale.

We estimate that our current cash resources, including the \$40.0 million license fee we received from Merck in January 2008, interest on these funds and product revenue from the sale of FARESTON<sup>®</sup>, will be sufficient to meet our projected operating requirements through at least the first quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaborations with Ipsen Limited, or Ipsen, and Merck, nor does it include any funding that we may receive under potential future collaboration arrangements with other pharmaceutical companies or potential future issuances and sales of our securities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our and/or our collaborators' clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaborative arrangements with Merck and Ipsen;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Merck and Ipsen;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our collaborators may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, as well as through interest income earned on our cash balances and short-term investments, and revenues from the sale of FARESTON®.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and/or licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or product candidates, or we may be required to grant licenses on terms not favorable to us.

### **Risks Related to Development of Product Candidates**

***We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or if our or our collaborators' clinical trials do not demonstrate safety and efficacy in humans.***

Preclinical and clinical testing is expensive, can take many years and has an uncertain outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. Typically, the failure rate for development candidates is high. Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned clinical trials will begin on time, will need to be restructured or will be completed on schedule, if at all.

In clinical studies the efficacy and/or safety results from the trial may be insufficient to support the filing or approval of a new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA.

We or our collaborators may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our or our collaborators' ability to commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our collaborators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- preclinical or clinical trials may produce negative or inconclusive results, which may require us or our collaborators to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;
- registration or enrollment in clinical trials may be slower than we currently anticipate, resulting in significant delays;
- we or our collaborators may suspend or terminate clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- our product candidates may not have the desired effects or may include undesirable side effects.

If any of these events were to occur and, as a result, we or our collaborators have significant delays in or termination of clinical trials, our costs could increase and our ability to generate revenue could be impaired, which would adversely impact our financial results.

For some of the indications for which we intend to conduct or are currently conducting clinical trials for our product candidates, we do not have evidence from prior preclinical studies in animals or clinical trials in humans of

the potential effectiveness of such product candidates for such indications. In the absence of preclinical or clinical data, our beliefs regarding the potential effectiveness of our product candidates for these indications is generally based on pharmacokinetic data and analyses and pharmacological rationales. Our or our collaborators' preclinical or clinical trials may produce negative or inconclusive results that would not support our belief regarding the potential effectiveness of our product candidates.

***If we or our collaborators observe serious or other adverse events during the time our product candidates are in development or after our products are approved and on the market, we or our collaborators may be required to perform lengthy additional clinical trials, may be denied regulatory approval of such products, may be forced to change the labeling of such products or may be required to withdraw any such products from the market, any of which would hinder or preclude our ability to generate revenues.***

In our Phase III clinical trial for ACAPODENE<sup>®</sup> 20 mg for the for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN, some patients have experienced venous thromboembolic events, or VTEs, such as deep vein thromboses and pulmonary embolisms, as well as myocardial infarctions, or heart attacks, which have been considered by investigators as possibly related to treatment with ACAPODENE<sup>®</sup> 20 mg. Because this trial is blinded, we cannot establish whether these patients received placebo or ACAPODENE<sup>®</sup> 20 mg in this trial. In addition, although the results from our Phase III clinical trial for ACAPODENE<sup>®</sup> 80 mg for the treatment of multiple serious side effects of androgen deprivation therapy, or ADT, showed that the drug had a favorable safety profile and was well tolerated, there were a higher number of VTEs in the ACAPODENE<sup>®</sup> 80 mg treatment group 17 (2.4%) versus 7 (1.02%) in the placebo group. Even though the majority of VTEs occurred in men who were at high risk for a VTE (including: age greater than 80 years, history of VTEs, recent surgical procedure and immobilization) and our results showed that the number of VTE's in men without major risk factors for VTEs was 3 in the ACAPODENE<sup>®</sup> 80 mg treatment group versus 2 in the placebo group, the FDA will consider the overall safety profile when making its determination to grant approval and the requirement of any potential warnings in the label if approval is granted.

There have been no drug-related serious adverse events related to our other product candidates. In addition, in our Phase II clinical trial for Ostarine<sup>™</sup>, we observed mild elevations of hepatic enzymes in a few patients, and in our preclinical studies for Ostarine<sup>™</sup>, only at the highest doses, we observed expected selective effects on the reproductive and other target organs in the male population consistent with the stimulating and inhibiting effects on the androgen receptor which is located in these organs.

If the incidence of these events increases in number or severity, if a regulatory authority believes that these events constitute an adverse effect caused by the drug, or if other effects are identified during clinical trials that we are currently conducting, during clinical trials that we or our collaborators may conduct in the future or after any of our product candidates are approved and marketed:

- we or our collaborators may be required to conduct additional preclinical or clinical trials, make changes in labeling of any such approved products, reformulate any such products, or implement changes to or obtain new approvals of our contractors' manufacturing facilities;
- regulatory authorities may be unwilling to approve our product candidates or may withdraw approval of our products;
- we may experience a significant drop in the sales of the affected products;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action suits.

Any of these events could prevent approval or harm sales of the affected product candidates or products, or could substantially increase the costs and expenses of commercializing and marketing any such products.

### **Risks Related to Our Dependence on Third Parties**

***If third parties do not manufacture our product candidates in sufficient quantities, in the required timeframe, and at an acceptable cost, clinical development and commercialization of our product candidates would be delayed.***

We do not currently own or operate manufacturing facilities, and we rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any product candidates on a timely and competitive basis.

We have agreed to purchase from Orion Corporation, or Orion, our worldwide requirements of toremifene, the active pharmaceutical ingredient in ACAPODENE<sup>®</sup>, in a finished tablet form at specified transfer prices under a license and supply agreement. Similarly, Ipsen has agreed to purchase from Orion ACAPODENE<sup>®</sup> tablets for clinical testing and commercial sale in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we refer to collectively as the European Territory, under an amended supply agreement with Orion. As such, both we and Ipsen rely on Orion as the single source supplier of ACAPODENE<sup>®</sup>.

In the event that Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy, we would not be able to manufacture ACAPODENE<sup>®</sup> until the expiration of Orion's patents with respect to the composition of matter of toremifene, the active pharmaceutical ingredient in ACAPODENE<sup>®</sup>. Although Orion's composition of matter patents within the European Territory have expired, and as such, would not prevent Ipsen from manufacturing ACAPODENE<sup>®</sup> within the European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to Ipsen or to assist Ipsen in developing manufacturing capabilities to meet Ipsen's supply needs if Ipsen is in material breach of its supply agreement with Orion. Although we and Ipsen have agreed to collaborate with each other in the event either of our supply rights are terminated by Orion for any reason, a disruption in the supply of ACAPODENE<sup>®</sup> could delay the development of and impair our and Ipsen's ability to commercialize ACAPODENE<sup>®</sup>. In addition, Orion may terminate its obligation to supply us and Ipsen with toremifene if Orion ceases its manufacture of toremifene permanently, or Orion may terminate its obligation to supply us with toremifene if ACAPODENE<sup>®</sup> is not approved for commercial sale in the United States prior to December 31, 2009. If such termination occurs because Orion is no longer manufacturing toremifene, or because such regulatory approval is not obtained prior to the specified date, we and Ipsen will have the right to manufacture ACAPODENE<sup>®</sup>, but any arrangements we make for an alternative supply would still have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for ACAPODENE<sup>®</sup>. We and Ipsen have mutually agreed to cooperate in the manufacture of ACAPODENE<sup>®</sup> in the event Orion ceases manufacture of toremifene for any of the above-mentioned reasons.

We also rely on Orion to cooperate with us in the filing and maintenance of regulatory filings with respect to the manufacture of ACAPODENE<sup>®</sup>. Orion may terminate its obligation to assist us in obtaining and maintaining regulatory approval of ACAPODENE<sup>®</sup> if we do not receive regulatory approval for ACAPODENE<sup>®</sup> in the United States prior to December 31, 2009. If Orion terminates its obligation to cooperate in these activities, or does not cooperate with us or otherwise does not successfully file or maintain these regulatory filings, we would be required to make arrangements with a qualified alternative supplier, which could delay or prevent regulatory approval of ACAPODENE<sup>®</sup>.

We have relied on third party vendors for Ostarine<sup>™</sup>. We have executed agreements with third party contractors for the manufacture of Ostarine<sup>™</sup> drug substance and the supply of Ostarine<sup>™</sup> drug product for our Phase II clinical trial for the treatment of cancer cachexia. However, Merck has assumed primary manufacturing responsibilities for Ostarine<sup>™</sup> and other SARM products developed under our exclusive license and collaboration agreement with Merck. If our current supply of Ostarine<sup>™</sup> becomes unusable or if our Ostarine<sup>™</sup> supply is not sufficient to complete our clinical trials and Merck does not manufacture and supply sufficient quantities of clinical trial materials to support our clinical trials, we could experience a delay in conducting clinical trials of Ostarine<sup>™</sup> or other SARM product candidates. We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at all. If we are unable to continue relationships with Orion for ACAPODENE<sup>®</sup> and Merck for Ostarine<sup>™</sup> and other SARM product candidates, or to do so at an acceptable cost, or if these or other suppliers fail to meet our requirements for Ostarine<sup>™</sup> or other SARM product candidates for any

reason, we would be required to obtain alternate suppliers. However, we may not be permitted to obtain alternate suppliers for ACAPODENE® under our license agreement with Orion if Orion terminates its supply of ACAPODENE® due to our uncured material breach or bankruptcy. Any inability to obtain alternate suppliers, including an inability to obtain approval from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

***Use of third-party manufacturers may increase the risk that we will not have adequate supplies of our product candidates.***

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us;
- drug product supplies not meeting the requisite requirements for clinical trial use; and
- the possible exercise by Orion of its right to terminate its obligation to supply us with toremifene:
  - if it permanently ceases manufacture of toremifene or if we do not obtain regulatory approval of ACAPODENE® in the United States prior to December 31, 2009; or
  - if Orion terminates due to our uncured material breach or bankruptcy.

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we and/or our collaborators may develop may compete with other product candidates and products for access to manufacturing facilities. For example, the active pharmaceutical ingredient in ACAPODENE® is also the active pharmaceutical ingredient in FARESTON®. Further, Orion has agreed to supply ACAPODENE® tablets to Ipsen for clinical trials and commercial supply in the European Territory. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of advanced breast cancer in postmenopausal women.

Our present or future manufacturing partners may not be able to comply with FDA-mandated current Good Manufacturing Practice regulations, other FDA regulatory requirements or similar regulatory requirements outside the United States. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

***We are dependent on our collaborative arrangement with Ipsen to develop and commercialize ACAPODENE® in the European Territory and are dependent on our collaborative arrangement with Merck for the joint research, development and commercialization of SARM compounds and products. We may also be dependent upon additional collaborative arrangements to complete the development and commercialization of some of our other product candidates. These collaborative arrangements may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.***

The loss of Ipsen or Merck as a collaborator in the development or commercialization of ACAPODENE® or SARM compounds and related SARM products, respectively, any dispute over the terms of our collaborations with Ipsen or Merck, or any other adverse developments in our relationships with Ipsen or Merck could materially harm our business and might accelerate our need for additional capital. For example, Ipsen is obligated to initiate and conduct appropriate clinical studies as required by the appropriate regulatory authorities in order to obtain marketing approvals of ACAPODENE® within the European Territory. Any failure on the part of Ipsen to initiate these studies



could delay the commercialization of ACAPODENE® within the European Territory. Likewise, with the exception of our Phase II clinical trial evaluating Ostarine™ for the treatment of cancer cachexia, Merck is responsible for conducting all clinical trials for SARM product candidates developed under the collaboration, and the failure of Merck to initiate these clinical trials would adversely affect the development of our SARM product candidates.

We may not be successful in entering into additional collaborative arrangements with other third parties. If we fail to enter into additional collaborative arrangements on favorable terms, it could delay or impair our ability to develop and commercialize our other product candidates and could increase our costs of development and commercialization.

Dependence on collaborative arrangements, including our arrangements with Ipsen and Merck for the development and commercialization of ACAPODENE® and SARM compounds and products, respectively, subjects us to a number of risks, including:

- we are not able to control either the amount and timing of resources that Ipsen devotes to ACAPODENE® or the amount of timing and resources that Merck devotes to SARM compounds and products developed under our collaboration with Merck;
- we may not be able to control the amount and timing of resources that our potential future partners may devote to our product candidates;
- our partners may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- under certain circumstances, Ipsen may not be required to commercialize ACAPODENE® in certain countries of the European Territory if Ipsen determines that it is not commercially reasonable for it to do so;
- pricing reimbursement constraints within the European Territory may diminish the prospects of our receiving royalty payments from Ipsen on aggregate net sales of ACAPODENE® in some or all of the countries within the European Territory;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for the compound or product candidate;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

***We may not realize the anticipated benefits from our collaborative arrangements with Ipsen and Merck.***

We may not receive any future milestone payments provided for under our collaborative arrangements with Ipsen and Merck if our agreements with them are terminated, if certain clinical development and regulatory milestones under our agreements with them are not achieved, with respect to our agreement with Ipsen, if Ipsen fails to develop and commercialize ACAPODENE® in the European Territory, or, with respect to our agreement with Merck, if we and Merck fail to develop and commercialize any of the SARMs included in or arising from our collaboration. In addition, even if required regulatory approvals are obtained, it is possible that neither Ipsen nor Merck will successfully market and sell ACAPODENE® or any SARM products, respectively, in which case we would not receive royalties to the extent that we currently anticipate. Furthermore, our royalty rates under our collaboration and license agreement with Ipsen are subject to a possible reduction if a generic version of toremifene achieves

specified sales levels in a major country within the European Territory, and each of Ipsen and Merck may be entitled to offset a portion of any royalties due to us if Ipsen or Merck licenses patent rights from a third party that would otherwise be infringed by Ipsen's or Merck's use, manufacture, sale or import of toremifene or SARM compounds, respectively.

Under our agreement with Ipsen, we and Ipsen have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed period of time subsequent to the time of the first commercial launch of ACAPODENE® within the European Territory. We and Ipsen have also agreed to grant to the other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties agree on. However, we cannot assure you that we will be able to reach an agreement with Ipsen on reasonable terms, or at all, for any new SERM-based products.

Under our agreement with Merck, we and Merck have agreed that neither party will engage in the development and commercialization of SARMS with any third party for an agreed upon period of time. However, we cannot assure you that we and Merck will be able to successfully develop new SARM products or identify new indications for existing and/or future SARM products under our collaboration with Merck. Additionally, Merck has the right to terminate our agreement with Merck for any reason after a specified period of time with prior written notice, and Ipsen has the right to terminate our agreement with Ipsen with 12 months prior written notice for any reason and with 30 days prior written notice as a result of legitimate and documented safety concerns. Both Ipsen and Merck may terminate their agreements with us following our uncured material breach or bankruptcy. If our agreements with Ipsen and Merck are terminated, the anticipated future benefits to us from these agreements would be eliminated, the development and commercialization of ACAPODENE® in the European Territory and the development and commercialization of our SARM product candidates could be delayed, and our costs of development would increase. For example, Merck's obligation to pay us \$15.0 million in guaranteed cost reimbursements for research funding over a three year period is subject to our exclusive license and collaboration agreement with Merck not being terminated for cause and there not occurring certain change of control events involving us during such three-year period. In any such or similar events, we may not realize the anticipated benefits from our collaborative arrangements with Ipsen and Merck.

***If third parties on whom we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or to commercialize our product candidates.***

We do not have the ability to independently conduct clinical trials for our product candidates, and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third parties to assist with our preclinical development of product candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

### **Risks Related to Our Intellectual Property**

***Our license agreement with Orion excludes the use of toremifene in humans to treat breast cancer outside the United States and may limit our ability to market ACAPODENE® for human uses of toremifene outside the United States.***

Our exclusive license and supply agreement from Orion excludes the use of toremifene for the treatment of breast cancer outside the United States. Orion has licensed to other parties the right to market, sell and distribute toremifene for the treatment of advanced breast cancer outside the United States and could license additional parties to market, sell and distribute toremifene for this indication outside the United States.

Under the terms of our license agreement with Orion, Orion may require us and Ipsen to modify our final ACAPODENE® development plans for specified major markets outside the United States if those development plans could adversely affect Orion's or Orion's other licensees' activities related to FARESTON® for breast cancer outside the United States or toremifene-based animal health products. Although we do not believe that our or Ipsen's

development plans adversely affect these activities, any future modifications to our or Ipsen's plans imposed by Orion may limit our and Ipsen's ability to maximize the commercial potential of ACAPODENE®.

Furthermore, we and our affiliates are prohibited from marketing or selling products containing toremifene or related SERM compounds for human use in the United States and other major countries located outside the European Union during the term of Orion's patents covering toremifene in such countries, which in the United States expire in September 2009. The binding effect of this noncompetition provision on us and our affiliates may make it more difficult for us to be acquired by some potential buyers during the relevant time periods even if we determine that a sale of the company would be in the best interests of our stockholders.

***If some or all of our, or our licensors', patents expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not yield issued patents or yield patents with narrow claims, or if we are prevented from asserting that the claims of an issued patent cover a product of a third party, we may be subject to competition from third parties with products with the same active pharmaceutical ingredients as our product candidates.***

Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection for our product candidates, the methods for treating patients in the product indications using these product candidates and the methods used to synthesize these product candidates. We will be able to protect our product candidates and the methods for treating patients in the product indications using these product candidates from unauthorized use by third parties only to the extent that we or our exclusive licensors own or control such valid and enforceable patents or trade secrets. Additionally, Ipsen's ability to successfully market ACAPODENE® within a substantial portion of the European Territory may depend on having marketing and data exclusivity from the appropriate regulatory authorities.

Our rights to certain patent applications relating to SARM compounds that we have licensed from the University of Tennessee Research Foundation, or UTRF, are subject to the terms of UTRF's inter-institutional agreements with The Ohio State University, or OSU, and our rights to future related improvements in some instances are subject to UTRF's exercise of exclusive options under its agreements with OSU for such improvements, which UTRF is required to do at our request. In addition, under the terms of our agreements with the diagnostic companies to which we provided clinical samples from our Phase IIb and Phase III clinical trials of ACAPODENE®, we will not obtain any intellectual property rights in any of their developments, including any test developed to detect high grade PIN or prostate cancer.

Even if our product candidates and the methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope and support in the specification, the patents will provide protection only for a limited amount of time. For example, the patent that we have licensed from Orion covering the composition of matter of toremifene expires in the United States in September 2009. Foreign counterparts of this patent have either already expired or will expire in Australia, Italy, Sweden and Switzerland in 2008, that is, before we or Ipsen will receive regulatory approval to commercialize ACAPODENE®. As a result, outside the United States and in the United States after 2009, we will need to rely primarily on the protection afforded by method of use patents relating to the use of ACAPODENE® for the relevant product indications that have been issued or may be issued from our owned or licensed patent applications. Also, within the European Union, Ipsen may need to rely primarily on the protection afforded by marketing and data exclusivity for the ACAPODENE® products to be sold within the countries comprising the European Union. To date, most of our applications for method of use patents filed for ACAPODENE® outside of the United States are still pending and have not yielded issued patents. Loss of marketing and data exclusivity for the ACAPODENE® products to be commercialized within the European Union could adversely affect its ability to successfully commercialize these products. We are not eligible for any such exclusivity or further extension of the composition of matter patent of toremifene licensed to us by Orion in the United States.

Our and our licensors' ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensors, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our

intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Even if patents are issued to us or our licensors regarding our product candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid or unenforceable or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create noninfringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing another less burdensome pathway to approval.

We also rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

***If we lose our licenses from Orion and UTRF, we may be unable to continue our business.***

We have licensed intellectual property rights and technology from Orion and UTRF under our license agreements with each of them. Each of these license agreements may be terminated by the other party if we are in breach of our obligations under, or fail to perform any terms of, the agreement and fail to cure that breach. If any of these agreements were terminated, then we may lose our rights to utilize the technology and intellectual property covered by that agreement to market, distribute and sell our licensed products, which may prevent us from continuing our business. Additionally, the termination of our UTRF license related to SARM technology could lead to a termination of our exclusive license and collaboration agreement with Merck, which would terminate our rights to any potential milestone or royalty payments from Merck. In addition, the termination of our UTRF license for chemoprevention of prostate cancer could lead to a termination of our license and collaboration agreement with Ipsen, which would terminate our rights to any potential milestone or royalty payments from Ipsen.

***Off-label sale or use of toremifene products could decrease sales of ACAPODENE® and could lead to pricing pressure if such products become available at competitive prices and in dosages that are appropriate for the indications for which we and Ipsen are developing ACAPODENE®.***

In all countries in which we hold or have licensed rights to patents or patent applications related to ACAPODENE®, the composition of matter patents we license from Orion will expire before our method of use patents, and in some countries outside the United States, the composition of matter patents have already expired. Our method of use patents may not protect ACAPODENE® from the risk of off-label sale or use of other toremifene products in place of ACAPODENE®. Physicians are permitted to prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those uses tested and approved by the FDA or its equivalent. Such off-label uses are common across medical specialties and are particularly prevalent for cancer treatments. Any off-label sales of toremifene may adversely affect our or Ipsen's ability to generate revenue from the sale of ACAPODENE®, if approved for commercial sale.

Even in the event that patents are issued from our pending method of use patent applications, after the expiration of the patent covering the composition of matter of toremifene in a particular country, competitors could market and sell toremifene products for uses for which FARESTON® has already been approved. Thus, physicians in such countries would be permitted to prescribe these other toremifene products for indications that are protected by our method of use patents or patents issuing from pending patent applications, even though these other toremifene products would not have been approved for those uses, and in most cases, the physician would not be liable for contributing to the infringement of our patents. Moreover, because Orion has licensed and could further license other parties to market, sell and distribute toremifene for breast cancer outside the United States, physicians in such countries could prescribe these products sold pursuant to another Orion license off-label. This further increases the

risk of off-label competition developing for ACAPODENE® for the indications for which we and Ipsen are developing this product candidate. In addition, if no patents are issued with respect to our pending method of use patent applications related to the use of ACAPODENE® in the countries outside of the United States where these applications are currently pending, after the expiration of the patent covering the composition of matter of toremifene in a particular country, we would have no patent to prevent competitors from marketing and selling generic versions of toremifene at doses and in formulations equivalent to ACAPODENE® for the indications covered by our pending method of use patent applications. Also, regulatory authorities may not recognize marketing and data exclusivity for ACAPODENE® in the European Union for the treatment of prostate cancer and multiple side effects resulting from androgen deprivation therapy. If generic versions of toremifene are able to be sold in countries within the European Territory for the indications for which Ipsen anticipates marketing ACAPODENE®, the royalties to be paid to us by Ipsen will be reduced if the total generic sales exceed a certain threshold for a certain period of time. Similarly, the royalties we will be paying to Orion for its licensing and supply of toremifene will be reduced if generic sales thresholds are reached.

***If we infringe intellectual property rights of third parties, it may increase our costs or prevent us from being able to commercialize our product candidates.***

There is a risk that we are infringing the proprietary rights of third parties because numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields that are the focus of our drug discovery, development, and manufacture and process synthesis efforts. Others might have been the first to make the inventions covered by each of our or our licensors' pending patent applications and issued patents and might have been the first to file patent applications for these inventions. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us or our licensors, which may later result in issued patents that cover the production, manufacture, synthesis, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, synthesis, commercialization, formulation or use of our product candidates may infringe existing patents of which we are not aware. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.

As a result of intellectual property infringement claims, or to avoid potential claims, we might:

- be prohibited from selling or licensing any product that we and/or collaborators may develop unless the patent holder licenses the patent to us, which the patent holder is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder; or
- be required to redesign the formulation of a product candidate so it does not infringe, which may not be possible or could require substantial funds and time.

In addition, under our collaboration and license agreement with Ipsen and our exclusive license and collaboration agreement with Merck, Ipsen and Merck may be entitled to offset a portion of any royalties due to us in any calendar year on account of product sales to pay for costs incurred by Ipsen or Merck to obtain a license to any dominant intellectual property rights that are infringed by the products at issue.

### **Risks Related to Regulatory Approval of Our Product Candidates**

***If we or our collaborators are not able to obtain required regulatory approvals, we or our collaborators will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.***

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us or our collaborators from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. In addition, we will not receive a substantial majority of the milestone payments provided under our collaboration and license agreement with Ipsen or any royalty payments if Ipsen is unable to obtain the

necessary regulatory approvals to commercialize ACAPODENE® within the European Territory. Likewise, we may not receive a majority of the milestone payments or any royalty payments provided for under our exclusive license and collaboration agreement with Merck if Merck is not able to obtain the necessary regulatory approvals to commercialize any SARM products, including Ostarine™, developed under the collaboration. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For example, the Food and Drug Administration Amendments Act of 2007, or the FDA Amendments Act, which was enacted in September 2007, expands the FDA's authority to regulate drugs throughout the product life cycle, including enhanced authority to require post-approval studies and clinical trials. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements and restrict sales and promotional activities. This new legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us or our collaborators to obtain approval of our product candidates. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. The approval may also impose risk evaluation mitigation strategies, or REMS, on a product if the FDA believes there is a reason to monitor the safety of the drug in the market place. REMS may include requirements for additional training for health care professionals, safety communication efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. The FDA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Furthermore, the approval procedure and the time required to obtain approval varies among countries and can involve additional testing beyond that required by the FDA. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. For example, we completed our Phase III clinical trial of ACAPODENE® to treat multiple side effects of androgen deprivation therapy and are conducting our Phase III clinical trial of ACAPODENE® for the prevention of prostate cancer in high risk men with high grade PIN, under Special Protocol Assessments, or SPAs, from the FDA. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the FDA to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of a NDA. However, there are circumstances under which we may not receive the benefits of a SPA, notably if the FDA subsequently identifies a substantial scientific issue essential to determining the product's safety or efficacy. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, even if we file an application with the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We may not receive regulatory approval for the commercial sale of any of our product candidates that are in development for at least another year, if ever. Similarly, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market ACAPODENE® within the European Territory any sooner than we will achieve regulatory approval in the United States, and it may be thereafter. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or our collaborators from commercializing these product candidates in the United States or other countries. See the section entitled "Business - Government Regulation" under Part I, Item 1 above for additional information regarding risks associated with marketing approval, as well as risks related to post-approval requirements.

### **Risks Related to Commercialization**

*The commercial success of any products that we and/or our collaborators may develop will depend upon the degree of market acceptance among physicians, patients, healthcare payors and the medical community.*

Any products that we and/or our collaborators may develop may not gain market acceptance among physicians, patients, health care payors and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues or receive royalties to the extent we currently anticipate, and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and safety results in clinical trials;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

*Our only marketed product generating revenue is FARESTON<sup>®</sup>, which is subject to a number of risks. These risks that may cause sales of FARESTON<sup>®</sup> to continue to decline.*

FARESTON<sup>®</sup> is currently our only marketed product. Sales of FARESTON<sup>®</sup> in the United States have been declining and we anticipate that they will continue to do so. Sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as aromatase inhibitors have gained market share. We believe that aromatase inhibitors will continue to capture breast cancer market share from SERMs, including from FARESTON<sup>®</sup>, resulting in a continued decline in FARESTON<sup>®</sup> sales. Continued sales of FARESTON<sup>®</sup> also could be impacted by many other factors. The occurrence of one or more of the following risks may cause sales of FARESTON<sup>®</sup> to decline more than we currently anticipate:

- the loss of the availability of Orion's website to market FARESTON<sup>®</sup>, which is an important source of advertising;
- the loss of one or more of our three largest wholesale drug distributors, which together accounted for approximately 93% of our gross product sales of FARESTON<sup>®</sup> for the year ended December 31, 2007;
- the continued success of competing products, including aromatase inhibitors;
- the loss of coverage or reimbursement for FARESTON<sup>®</sup> from Medicare and Medicaid, private health insurers or other third-party payors;
- exposure to product liability claims related to the commercial sale of FARESTON<sup>®</sup>, which may exceed our product liability insurance;
- the failure of Orion to maintain regulatory filings or comply with applicable FDA requirements with respect to FARESTON<sup>®</sup>;
- the ability of third parties to market and sell generic toremifene products that will compete with FARESTON for the treatment of breast cancer after the composition of matter patents that we license from Orion expire in the United States in September 2009;

- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON<sup>®</sup>; and
- our inability to manufacture FARESTON<sup>®</sup> until Orion's patents with respect to the composition of matter of toremifene expire if Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy.

***If we are unable to expand our sales and marketing capabilities or establish and maintain agreements with third parties to market and sell our product candidates, we may be unable to generate product revenue from such candidates.***

We have limited experience as a company in the sales, marketing and distribution of pharmaceutical products. There are risks involved with building our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, building a sales force is expensive and time-consuming and could delay any launch of a product candidate. We are relying on Ipsen to market and distribute our ACAPODENE<sup>®</sup> product candidates through Ipsen's established sales and marketing network within the European Territory. If our collaboration and license agreement with Ipsen is terminated for any reason, our ability to sell our ACAPODENE<sup>®</sup> product candidates in the European Territory would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell our ACAPODENE<sup>®</sup> product candidates in the European Territory. Currently, we do not have a partner outside of the European Territory and our success in regions other than the European Territory may be dependent on our ability to find suitable partners in other regions of the world. Similarly, we are relying on Merck for the commercialization of any SARM products developed under our collaboration with Merck and if our exclusive license and collaboration agreement with Merck is terminated for any reason, our ability to successfully market and sell any of our SARM product candidates would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell any SARM products that we may develop, including Ostarine<sup>™</sup>. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

***If we or our collaborators are unable to obtain adequate coverage and reimbursement from third-party payors for products we sell at acceptable prices, our revenues and prospects for profitability will suffer.***

Many patients will not be capable of paying for any products that we and/or our collaborators may develop and will rely on Medicare and Medicaid, private health insurers and other third-party payors to pay for their medical needs. If third-party payors do not provide coverage or reimbursement for any products that we and/or our collaborators may develop, our revenues and prospects for profitability may suffer. For example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 created a prescription drug benefit program for Medicare recipients. The prescription drug program established by this legislation may have the effect of reducing the prices that we or our collaborators are able to charge for products we and/or our collaborators develop and sell through the program. This legislation may also cause third-party payors other than the federal government, including the states under the Medicaid program, to discontinue coverage for products that we and/or our collaborators may develop or to lower the amount that they pay. In addition, members of the United States Congress have stated their desire to reduce the government's cost for reimbursements of prescription drugs by amending this legislation.

State Medicaid programs generally have outpatient prescription drug coverage, subject to state regulatory restrictions, for the population eligible for Medicaid. The availability of coverage or reimbursement for prescription drugs under private health insurance and managed care plans varies based on the type of contract or plan purchased.

A primary trend in the United States health care industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our or our collaborators' commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we and/or our collaborators may develop or sell.



Cost-control initiatives could decrease the price we might establish for products that we or our collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Another development that may affect the pricing of drugs is proposed congressional action regarding drug reimportation into the United States. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug reimportation into the United States under some circumstances from foreign countries, including countries where the drugs are sold at a lower price than in the United States. Proponents of drug reimportation may attempt to pass legislation which would directly allow reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, they could decrease the price we or our collaborators receive for any products that we and/or our collaborators may develop, negatively affecting our revenues and prospects for profitability.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any products that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any product that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products for which we obtain or hold marketing approvals.

We have product liability insurance that covers our clinical trials and commercial products up to a \$25.0 million annual aggregate limit. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

***If our competitors are better able to develop and market products than any products that we and/or our collaborators may develop, our commercial opportunity will be reduced or eliminated.***

We face competition from commercial pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we and/or our collaborators may develop. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair our or our collaborators' ability to commercialize our product candidates.

Various products are currently marketed or used off-label for some of the diseases and conditions that we are targeting, and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish our or our collaborators' ability to market and sell any products that we and/or our collaborators may develop. For example, although there are no products that have been approved by the FDA to treat multiple side effects of androgen deprivation therapy, we are aware of a number of drugs marketed by Eli Lilly (Evista®), Merck (Fosamax®), Sanofi-Aventis and Procter & Gamble (Actonel®), Wyeth Pharmaceuticals (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and Bristol Myers Squibb (Megace®) that are prescribed to treat single side effects of androgen deprivation therapy; that external beam radiation and tamoxifen are used to treat breast pain

and enlargement, or gynecomastia; and that Amgen is developing a product candidate for the treatment of osteoporosis in prostate cancer patients. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in high risk men with high grade PIN, GlaxoSmithKline is conducting a Phase III study for Avodart® on prostate cancer prevention in men with elevated prostate specific antigen. In addition, there are nutritional supplement studies (for example, selenium) investigating prostate cancer prevention in men with high grade PIN. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting from cancer, there are drugs marketed by Steris Laboratories and Savient Pharmaceuticals that are being prescribed off-label for the treatment of some types of muscle wasting from cancer. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle wasting. There are other SARM product candidates in development that may compete with our product candidates. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine™. This could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

#### **Risks Related to Employees and Growth**

***If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop or commercialize our product candidates.***

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. If we are not able to attract and keep senior management and key scientific personnel, particularly Dr. Mitchell S. Steiner, we may not be able to successfully develop or commercialize our product candidates. All of our employees are at-will employees and can terminate their employment at any time. We do not carry “key person” insurance covering members of senior management, other than \$25 million of insurance covering Dr. Steiner.

***We will need to hire additional employees in order to continue our clinical trials and commercialize our product candidates. Any inability to manage future growth could harm our ability to commercialize our product candidates, increase our costs and adversely impact our ability to compete effectively.***

In order to continue our clinical trials and commercialize our product candidates, we will need to expand the number of our managerial, operational, financial and other employees. We currently anticipate that we will need between 150 and 250 additional employees by the time that ACAPODENE® is initially commercialized, including 50 to 100 sales representatives. The competition for qualified personnel in the biotechnology field is intense.

Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

#### **Risks Related to Our Common Stock**

***Market volatility may cause our stock price and the value of your investment to decline.***

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be so in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- adverse results or delays in our clinical trials;

- the timing of achievement of our and our collaborators' clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our sales and marketing activities;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- developments with respect to our collaborations with Ipsen and Merck;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- regulatory developments in the United States and foreign countries;
- changes in the structure of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- announcements of technological innovations or new products by us or our competitors;
- market conditions for the biotechnology or pharmaceutical industries in general;
- actual or anticipated fluctuations in our results of operations;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

***Our officers, directors and largest stockholders have the ability to control all matters submitted to stockholders for approval.***

As of January 31, 2008, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 68.2% of our outstanding common stock and our officers and directors alone beneficially owned approximately 47.4% of our outstanding common stock. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors

and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

*Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.*

Provisions in our certificate of incorporation and our bylaws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a classified Board of Directors;
- a prohibition on actions by our stockholders by written consent;
- the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors; and
- limitations on the removal of directors.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Finally, these provisions establish advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders.

*A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.*

For the 12-month period ended December 31, 2007, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 160,000 shares. As a result, future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then-prevailing market price of our common stock. As of December 31, 2007, we had 36,216,263 shares of common stock outstanding.

Moreover, J.R. Hyde, III, and Oracle Partners, L.P., two of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 10.8 million shares of common stock they hold in the aggregate which are subject to registration rights or to include these shares in registration statements that we may file for ourselves or other stockholders. In addition, we filed a registration statement covering the 1,285,347 shares of common stock that we issued to Merck in December 2007. Finally, all shares of common stock that we may issue under our employee benefit plans can be freely sold in the public market upon issuance.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

## **ITEM 2. PROPERTIES**

We sublease approximately 53,000 square feet of laboratory and office space in Memphis, Tennessee, under an operating lease through December 31, 2008 with an option to extend for up to two additional years. This lease is terminable by either party on 90 days' notice. In December 2007, we entered into a sublease for approximately 31,000 square feet of additional office space in Memphis, Tennessee, under an operating lease through April 30, 2015. We have an option to cancel this sublease beginning December 31, 2010.

## **ITEM 3. LEGAL PROCEEDINGS**

We are not currently involved in any material legal proceedings.

## **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Not applicable.

## **PART II**

## **ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

### **Market for Registrant's Common Equity**

Our common stock began trading on The NASDAQ Global Market under the symbol "GTXI" on February 3, 2004. Prior to that date, there was no established public trading market for our common stock. The following table presents, for the periods indicated, the high and low closing sales prices per share of our common stock as reported on The NASDAQ Global Market.

	2007		2006	
	High	Low	High	Low
First Quarter	\$ 22.95	\$ 15.83	\$ 12.08	\$ 7.57
Second Quarter	23.38	16.19	11.57	8.11
Third Quarter	18.36	14.25	9.53	7.71
Fourth Quarter	18.19	13.67	18.30	9.26

On March 5, 2008 the closing price of our common stock as reported on The NASDAQ Global Market was \$14.71 per share and there were approximately 68 holders of record of our common stock.

### **Performance Graph**

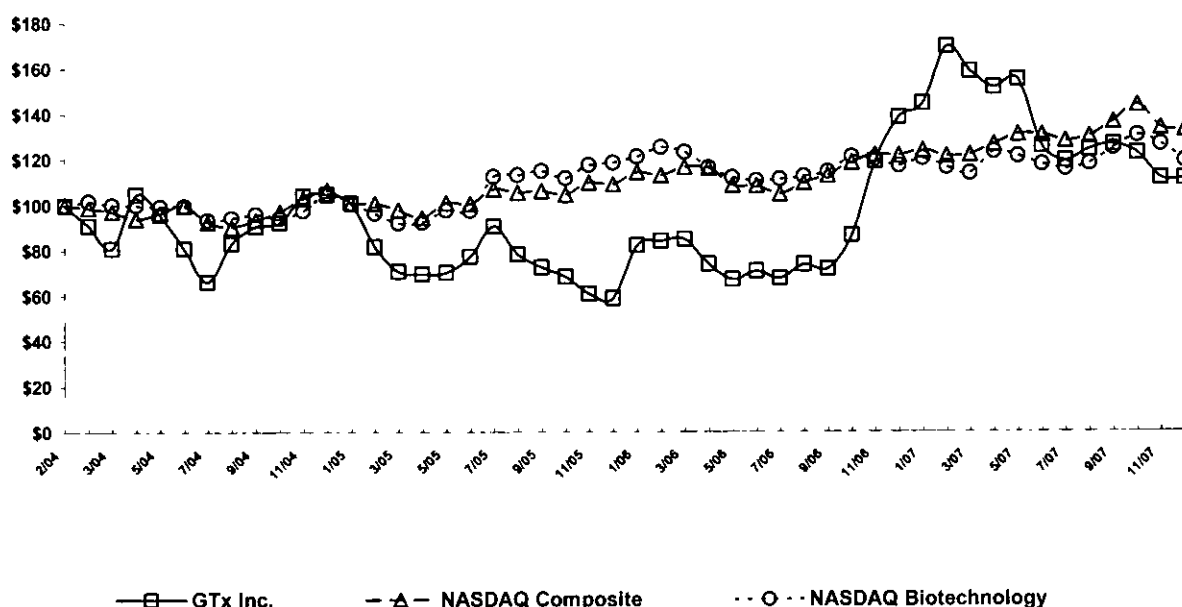
The rules of the SEC require that we include in our annual report to shareholders a line-graph presentation comparing cumulative stockholder returns on our common stock with a broad equity market index that includes companies whose equity securities are traded on the NASDAQ and either a published industry or line-of-business standard index or an index of peer companies selected by us. We have elected to use the NASDAQ Composite Index (which tracks the aggregate price performance of equity securities of companies traded on NASDAQ) and the NASDAQ Biotechnology Index (consisting of a group of approximately 130 companies in the biotechnology sector, including us) for purposes of the performance comparison that appears below.

The following graph shows the cumulative total stockholder return assuming the investment of \$100.00 at the closing prices on February 3, 2004, the first day of trading of the Company's common stock on the NASDAQ Global Market: (1) our common stock; (2) NASDAQ Composite Index and (3) NASDAQ Biotechnology Index. All values assume reinvestment of the full amounts of all dividends. No dividends have been declared on the Company's common stock. The closing sale price of our common stock on December 31, 2007 as reported on the NASDAQ Global Market was \$14.35.

The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

### COMPARISON OF 47 MONTH CUMULATIVE TOTAL RETURN\*

Among GTx Inc., The NASDAQ Composite Index  
And The NASDAQ Biotechnology Index



\* \$100 invested on 2/3/04 in stock or on 1/31/04 in index-including reinvestment of dividends.  
Fiscal year ending December 31.

The material in this section is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filing of GTx, Inc. under the Securities Act of 1933 or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in such filing.

### Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors.

## ITEM 6. SELECTED FINANCIAL DATA

You should read the selected financial data below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited financial statements, notes thereto and other financial information included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the years ended December 31, 2005, 2006 and 2007, and the balance sheet data at December 31, 2006 and 2007, are derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the years ended December 31, 2003 and 2004, and the consolidated balance sheet data at December 31, 2003, 2004 and 2005, are derived from our audited financial statements that are not included in this Annual Report on Form 10-K. Historical results are not indicative of the results to be expected in the future.

	Years Ended December 31,				
	2007	2006	2005	2004	2003
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenues:					
Product sales, net	\$ 1,076	\$ 1,357	\$ 2,445	\$ —	\$ —
Total collaboration revenue	6,050	6,148	1,337	1,867	—
Total revenues	7,126	7,505	3,782	1,867	—
Operating expenses:					
Cost of product sales	621	773	1,573	—	—
Research and development expenses	38,508	33,897	30,923	17,950	10,778
General and administrative expenses	13,501	11,352	9,845	7,211	3,559
Loss from operations	(45,504)	(38,517)	(38,559)	(23,294)	(14,337)
Interest income	5,145	3,007	1,720	946	143
Net loss	(40,359)	(35,510)	(36,839)	(22,348)	(14,194)
Accrued preferred stock dividends	—	—	—	(455)	(3,436)
Adjustment to preferred stock redemption value	—	—	—	17,125	(77,844)
Net loss attributable to common stockholders	\$ (40,359)	\$ (35,510)	\$ (36,839)	\$ (5,678)	\$ (95,474)
Net loss per share attributable to common stockholders:					
Basic	\$ (1.16)	\$ (1.14)	\$ (1.42)	\$ (0.25)	\$ (12.34)
Diluted	\$ (1.16)	\$ (1.14)	\$ (1.42)	\$ (0.93)	\$ (12.34)
	As of December 31,				
	2007	2006	2005	2004	2003
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 100,178	\$ 119,550	\$ 74,014	\$ 64,528	\$ 14,769
Working capital	132,932	111,363	70,030	61,298	12,775
Total assets	159,730	129,255	82,811	73,082	17,310
Cumulative redeemable convertible preferred stock	—	—	—	—	165,292
Accumulated deficit	(270,138)	(229,779)	(194,269)	(157,430)	(151,752)
Total stockholders' equity (deficit)	78,917	97,049	73,579	63,909	(150,231)

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Item 1A "Risk Factors" and elsewhere in this Annual Report on Form 10-K.*

### Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. In February 2008, we announced that the Phase III clinical trial results for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT showed that ACAPODENE® 80 mg reduced new morphometric vertebral fractures and met other key endpoints of bone mineral density, or BMD, lipid profiles and gynecomastia. In March 2008, we announced that the results from this Phase III clinical trial also showed that ACAPODENE® 80 mg demonstrated a reduction in hot flashes in a subset analysis. We expect to file a New Drug Application, or NDA, for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT with the U.S. Food and Drug Administration, or FDA, in 2008. We have licensed to Ipsen exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we refer to collectively as the European Territory, to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which we have licensed from Orion Corporation, or Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. We have entered into an exclusive license and collaboration agreement with Merck and Co., Inc., or Merck, establishing a global strategic collaboration for the discovery, development and commercialization of selective androgen receptor modulators, or SARMS, including Ostarine™. We believe that Ostarine™ and other SARM candidates, including GTx-838, have the potential to treat a variety of indications associated with muscle wasting and bone loss, including frailty, muscle wasting associated with aging, also known as sarcopenia, muscle wasting in cancer patients, known as cancer cachexia, osteoporosis and chronic kidney disease muscle wasting. We are currently evaluating Ostarine™ in a Phase II clinical trial for the treatment of cancer cachexia.

We also have an extensive preclinical pipeline generated from our own discovery program, including GTx-758, an oral luteinizing hormone, or LH, inhibitor being developed for the treatment of advanced prostate cancer, and GTx-878, an estrogen receptor beta agonist, a new class of drugs being developed for the treatment of benign prostatic hyperplasia, or BPH. We are planning to initiate Phase I clinical testing for GTx-758 by the end of 2008 and for GTx-878 in the first half of 2009.

We commenced a pivotal Phase III clinical trial of ACAPODENE® 80 mg under a Special Protocol Assessment, or SPA, with the FDA, for the treatment of multiple serious side effects of ADT in November 2003. The last patient completed the ADT clinical trial in November 2007. In February 2008, we announced that ACAPODENE® 80 mg reduced new morphometric vertebral fractures and met other key endpoints of BMD, lipid profiles and gynecomastia. Also, in March 2008, we announced that ACAPODENE® 80 mg demonstrated a reduction in hot flashes. We expect to file a NDA with the FDA in 2008.

In January 2005, we initiated a pivotal Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a SPA with the FDA. We will evaluate efficacy endpoints for the clinical trial at 36 months after completion of enrollment, and we anticipate



conducting a planned efficacy interim analysis after a certain number of cancer events have been recorded among study patients, which we currently expect to occur by the end of the first quarter of 2008. If the efficacy results from the planned interim analysis achieve the statistical outcome specified in the SPA ( $\alpha \leq 0.001$ ), we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the efficacy interim analysis, we will continue to collect efficacy data and safety data during the review process to satisfy the FDA's safety requirements set forth in the SPA. If the efficacy results from the planned interim analysis do not satisfy the specified statistical requirements in the SPA, we plan to continue the clinical trial for the full 36 month period and then determine whether the trial results satisfy the efficacy endpoints required by the SPA.

In our third clinical program, Ostarine<sup>TM</sup>, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss. In December 2006, we announced that Ostarine<sup>TM</sup> met its primary endpoint in a Phase II proof of concept, double blind, randomized, placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. We initiated a Phase II randomized, double blind, placebo controlled clinical trial evaluating Ostarine<sup>TM</sup> for the treatment of cancer cachexia in 150 patients diagnosed with non-small cell lung cancer, colorectal cancer, non-Hodgkin's lymphoma, or chronic lymphocytic leukemia. The clinical trial is being conducted at approximately 50 clinical sites in the United States, Argentina and Canada and we expect to receive data from this trial during the summer of 2008. We and Merck, through our SARM collaboration, will determine the development strategy of Ostarine<sup>TM</sup>, GTx-838 and other collaboration compounds.

In November 2007, we entered into a license and collaboration agreement with Merck which governs our and Merck's joint research, development and commercialization of SARM compounds and related SARM products, including SARMS currently being developed by us and Merck and those yet to be discovered, for all potential indications of interest. Under the agreement, we will conduct preclinical research of SARM compounds and products, and Merck will be primarily responsible for conducting and funding development and commercialization of products developed. We received an upfront licensing fee of \$40.0 million in January 2008, of which \$1.9 million was due to the University of Tennessee Research Foundation, or UTRF, as sublicense royalty. Merck also agreed to pay us \$15.0 million in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the agreement. We are also eligible to receive up to \$422.0 million in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine<sup>TM</sup>, as defined in the agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the agreement, upon the achievement of such development and regulatory approval milestones and assuming the continued effectiveness of the agreement. Merck also has agreed to pay us tiered royalties on net sales of products that may be developed under the agreement. On the date the agreement became effective in December 2007, we issued to Merck 1,285,347 newly-issued shares of our common stock for an aggregate purchase price of approximately \$30.0 million.

Our net loss for the year ended December 31, 2007 was \$40.4 million. Our net loss included FARESTON<sup>®</sup> net product sales of \$1.1 million and the recognition of collaboration revenue of \$6.1 million. We have financed our operations and internal growth primarily through public offerings and private placements of our common stock and preferred stock, as well as proceeds from our collaborations. We expect to continue to incur net losses as we continue our clinical development and research and development activities, apply for regulatory approvals, expand our sales and marketing capabilities and grow our operations.

### **Sales and Marketing**

We currently market FARESTON<sup>®</sup> (toremifene citrate 60 mg) tablets, which have been approved by the FDA for the treatment of metastatic breast cancer in postmenopausal women in the United States. In January 2005, we acquired from Orion the right to market FARESTON<sup>®</sup> tablets in the United States for the metastatic breast cancer indication. We also acquired from Orion a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. The active pharmaceutical ingredient in FARESTON<sup>®</sup> is the same as in ACAPODENE<sup>®</sup>, but in a different dose. We plan to build a specialty sales and marketing infrastructure, which we expect to include 50 to 100 sales representatives, to market ACAPODENE<sup>®</sup> to the relatively small and concentrated community of urologists and medical oncologists in the United States and to market FARESTON<sup>®</sup> to targeted prescribers, principally medical oncologists and other key specialists in the United States. We have partnered with

Ipsen to commercialize ACAPODENE® in Europe. We are currently seeking partners to market ACAPODENE® in Asia and other markets outside of the United States and Europe.

### Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses represented 74% of our total operating expenses for the year ended December 31, 2007. Research and development expenses include our expenses for personnel associated with our research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory affairs, quality assurance activities and license and royalty fees.

We expect that research and development expenditures will continue to increase in future years due to (1) obtaining regulatory approval of ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT for advanced prostate cancer, (2) the continuation of the pivotal Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, (3) the completion of the Phase II clinical trial evaluating Ostarine™ for the treatment of cancer cachexia, (4) the continued preclinical development of other product candidates, including GTx-758 and GTx-878 and (5) increases in research and development personnel.

There is a risk that any drug discovery and development program may not produce revenue. Moreover, because of uncertainties inherent in drug discovery and development, including those factors described in Item 1A "Risk Factors" of this Annual Report on Form 10-K, we may not be able to successfully develop and commercialize any of our product candidates.

Drug development in the United States is a process that includes several steps defined by the FDA. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an Investigational New Drug application which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant costs associated with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, a NDA may be submitted to the FDA. In responding to a NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may not grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval.

The successful development and commercialization of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development and commercialization of, or the period in which material net cash inflows are expected to commence from, any of our product candidates, including the product candidates developed or commercialized through our collaborations with Merck and Ipsen, due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

- the scope, rate of progress and cost of our and/or our collaborators' clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaborative arrangements with Merck and Ipsen;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Merck and

Ipsen;

- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our collaborators may develop;
- the effect of competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Any failure to complete the development of our product candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with completing our projects on schedule, or at all, and some consequences of failing to do so, are set forth under Part I, Item 1A "Risk Factors" of this Annual Report on Form 10-K.

### **General and Administrative Expenses**

Our general and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, information technology, investor relations and marketing functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal, accounting, public relations, and marketing services. General and administrative expenses also include insurance costs and FARESTON<sup>®</sup> selling and distribution expenses. We expect that our general and administrative expenses will increase in future periods as we add personnel, additional office space and other expenses to support the planned growth of our business. In addition, we plan to expand our sales and marketing efforts which will result in increased sales and marketing expenses in future years.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, income taxes, intangible assets, long-term service contracts and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

#### ***Revenue Recognition***

Our revenues consist of product sales of FARESTON<sup>®</sup> and revenues derived from our collaboration and license agreements.

We use revenue recognition criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements* as amended by SAB No. 104, (together, "SAB 104"), Statement of Financial Accounting Standards ("SFAS") No. 48, *Revenue Recognition When Right of Return Exists* ("SFAS No. 48"), Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverable* ("EITF

00-21”) and EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (“EITF 99-19”). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. We analyze agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and performance obligations such as joint steering committee participation and research and development activities, can be separated or whether all of the deliverables must be accounted for as a single unit of accounting in accordance with EITF 00-21. For these arrangements, we generally are not able to identify evidence of fair value for the undelivered elements and therefore recognize any consideration for a single unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is generally ratable over the performance period. The performance period is estimated at the inception of the agreement and is reevaluated at each reporting period. Cost reimbursements for research activities are recognized as collaboration revenue if the provisions of EITF 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured. Revenues from milestone payments for which we have no continuing performance obligations are recognized upon achievement of the performance milestone, as defined in the related agreement, provided the milestone is substantive and a culmination of the earnings process has occurred. Performance obligations typically consist of significant milestones in the development life cycle of the related products and technology, such as initiation of clinical trials, filing for approval with regulatory agencies and approvals by regulatory agencies.

We estimate the performance obligation period to be ten years for our collaboration agreement with Merck and five years for the development of ACAPODENE® for both the high grade PIN and ADT indications in the European Territory with Ipsen. The factors that drive the actual development period of a pharmaceutical product are inherently uncertain and include determining the timing and expected costs to complete the project, projecting regulatory approvals and anticipating potential delays. We use all of these factors in initially estimating the economic useful lives of our performance obligations, and we also continually monitor these factors for indications of appropriate revisions.

We recognize net product sales revenue from sales of FARESTON® less deductions for estimated sales discounts and sales returns. We recognize revenue from product sales when the goods are shipped and title and risk of loss pass to the customer and the other criteria of SAB No. 104 and SFAS No. 48 are satisfied. We account for rebates to certain governmental agencies as a reduction of product sales. We allow customers to return product within a specified time period prior to and subsequent to the product’s labeled expiration date. As a result, we estimate an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. We retained substantially the same wholesale customers of, and the distribution channel that was used by, another pharmaceutical company that distributed FARESTON® for six years prior to our obtaining the rights to market FARESTON® in January 2005. We also obtained historical product return trend information that we continue to update with our own product return data. We estimate the amount of product in the distribution channel which is expected to exceed its expiration date and be returned by the customer by receiving information from our three largest wholesale customers about the levels of FARESTON® inventory held by these customers. These three largest wholesale customers accounted for 93% of our gross product sales of FARESTON® for the year ended December 31, 2007. Based on this information, and other factors, we estimate the number of months of product on hand. At December 31, 2007 and December 31, 2006, our accrual for product returns was \$324,000 and \$415,000, respectively. If actual future results are different than our estimates, we may need to adjust our estimated accrual for product returns, which could have a material effect on our financial results in the period of the adjustment.

#### ***Research and Development Expenses***

We expense research and development costs in the period in which they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research, development and clinical trial studies on our behalf.

#### ***Patent Costs***

We expense patent costs, including legal fees, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in our statements of operations.

### ***Share-Based Compensation***

We have stock option plans that provide for the purchase of our common stock by certain of our employees and directors. Effective January 1, 2006, we adopted SFAS 123(R), *Share-Based Payment* ("SFAS 123R"), and began recognizing compensation expense for our share-based payments based on the fair value of the awards. Share-based payments include stock option grants under our stock option plans. Prior to January 1, 2006, we accounted for share-based compensation expense using the intrinsic value recognition method prescribed by Accounting Principles Board Opinion ("APB") No. 25, *Accounting for Stock Issued to Employees* ("APB 25") and SFAS No. 123, *Accounting for Share-based Compensation* ("SFAS 123"). Since we adopted SFAS 123R under the modified prospective and the prospective transition methods, results from prior periods have not been restated.

The determination of the fair value of share-based payment awards on the date of grant include the expected life of the award, the expected stock price volatility over the expected life of the awards, expected dividend yield, and risk-free interest rate. We estimate the expected life of options by calculating the average of the vesting term and contractual term of the options, as allowed by SAB 107. We estimate the expected stock price volatility based on the historical volatility of our common stock. Prior to 2007, we estimated the stock price volatility based on the average expected stock price volatility of other publicly traded biopharmaceutical companies as we believed that it was the best indicator of future volatility, since we had less than two years of our own historical stock price volatility. The risk-free interest rate is determined using U.S. Treasury rates where the term is consistent with the expected life of the stock options. Expected dividend yield is not considered as we have not made any dividend payments and have no plans of doing so in the foreseeable future. Forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Total share-based compensation expense for the year ended December 31, 2007 was \$2.2 million, of which \$1.0 million and \$1.2 million were recorded in the statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the years ended December 31, 2006 and 2005 was \$1.4 million and \$819,000, respectively. Included in share-based compensation expense for all periods presented is share-based compensation expense related to deferred compensation arrangements for our directors, which was \$183,000, \$140,000 and \$180,000 for the years ended December 31, 2007, 2006 and 2005, respectively. On the date of adoption of SFAS 123R, the unamortized balance of deferred stock compensation of \$1.7 million was reduced to zero with an offsetting adjustment to additional paid-in capital. At December 31, 2007, the total compensation cost related to non-vested awards not yet recognized was approximately \$5.0 million with a weighted average expense recognition period of 2.08 years.

### ***Income Taxes***

We account for deferred taxes by recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. This valuation allowance is estimated by management based on our projected future taxable income. The estimate of future taxable income is highly subjective. We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future. However, these assumptions may be inaccurate, and unanticipated events and circumstances may occur in the future. To the extent actual results differ from these estimates, our future results of operations may be affected. At December 31, 2007 and 2006, net of the valuation allowance, the net deferred tax assets were reduced to zero.

### ***Intangible Assets***

We account for our intangible assets in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, which requires that purchased intangible assets with finite lives be amortized over their estimated economic lives. Our purchased intangible assets, license fees, represent license fees paid to Orion in connection with entering into an amended and restated license and supply agreement and to UTRF in connection with entering into amended and restated license agreements. The Orion license fee is being amortized on a straight-line basis over the term of the

agreement which we estimate to be 16 years. The UTRF license fees are being amortized on a straight-line basis over the term of the agreements which we estimate to be approximately 14 years and 11.5 years. In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets to be Disposed of*, we review long-lived assets for impairment whenever events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. An impairment loss would be recognized when estimated future cash flows is less than the carrying amount. The cash flow estimates would be based on management's best estimates, using appropriate and customary assumptions and projections at the time.

### **Recent Accounting Pronouncements**

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109* ("FIN 48"), which clarifies the accounting for uncertainty in tax positions. FIN 48 requires the recognition of the impact of a tax position in the financial statements if that position is more likely than not of being sustained on audit based on the technical merits of the position. The provisions of FIN 48 were effective as of January 1, 2007. The adoption of the standard had no effect on our financial condition or results of operations.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The FASB has deferred the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. We do not expect the adoption of SFAS 157 will have a material impact on our financial position or results of operations.

In June 2007, the Emerging Issues Task Force issued EITF Issue No. 07-03, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development* ("EITF 07-03"). EITF 07-03 concludes that nonrefundable advance payments for future research and development activities should be deferred and capitalized and recognized as expense as the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. We do not expect the adoption of EITF 07-03 will have a material impact on our financial position or results of operations.

In November 2007, the Emerging Issues Task Force issued EITF Issue No. 07-01, *Accounting for Collaborative Arrangements* ("EITF 07-01"). EITF 07-01 concludes that the equity method of accounting cannot be applied to collaborative arrangement activities that are not conducted within a separate legal entity. Instead, the revenues and costs incurred with third parties in connection with the collaborative arrangement should be presented gross or net by the collaborators based on the criteria in EITF 99-19, and other applicable accounting literature. EITF 07-01 is effective for years beginning after December 15, 2008. We do not expect the adoption of EITF 07-01 will have a material impact on our financial position or results of operations.

### **Results of Operations**

#### ***Comparison of Years Ended December 31, 2007 and December 31, 2006***

**Revenues.** Revenues for the year ended December 31, 2007 were \$7.1 million as compared to \$7.5 million for the same period of 2006. Revenues for the year ended December 31, 2007 included net sales of FARESTON<sup>®</sup> marketed for the treatment of metastatic breast cancer and collaboration income from Ipsen and Merck. During the years ended December 31, 2007 and 2006, FARESTON<sup>®</sup> net sales were \$1.1 million and \$1.4 million, respectively, while costs of products sales were \$621,000 and \$773,000, respectively. The 21% decrease in net sales of FARESTON<sup>®</sup> for the year ended December 31, 2007, as compared to the same period of 2006, was due to a decrease in sales volume of 42%, which was offset by a 7% increase in sales price and a reduction in the provision for product returns. We expect FARESTON<sup>®</sup> sales will continue to decline in future periods, particularly as a result of aromatase inhibitors continuing to capture breast cancer market share from SERMs, including FARESTON<sup>®</sup>. Collaboration income was \$6.1 million for the year ended December 31, 2007, of which \$5.9 million and \$198,000

was from Ipsen and Merck, respectively. For the year ended December 31, 2006, collaboration income was \$6.1 million, of which \$4.3 million and \$1.8 million was from Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, and Ipsen, respectively. In December 2006, we reacquired full rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech, and our joint collaboration and license agreement with Ortho Biotech was terminated by mutual agreement of the parties. In connection with the termination of this agreement, we recognized the associated \$3.1 million balance of deferred revenue as additional collaboration revenue for the year ended December 31, 2006.

**Research and Development Expenses.** Research and development expenses increased 13.6% to \$38.5 million for the year ended December 31, 2007 from \$33.9 million for the year ended December 31, 2006. The following table identifies the research and development expenses for certain of our product candidates, as well as research and development expenses pertaining to our other research and development efforts for each of the periods presented. Included in "Other research and development" is a sublicense royalty of approximately \$1.9 million due to UTRF as a result of our collaboration with Merck. Research and development spending for past periods is not indicative of spending in future periods.

Program	Product Candidate/ Indication	Years Ended December 31,		Increase (Decrease)
		2007	2006	
(in thousands)				
SERM	ACAPODENE® 80 mg Multiple serious side effects of ADT	\$ 9,422	\$ 8,446	\$ 976
	ACAPODENE® 20 mg Prevention of prostate cancer in high risk men with high grade PIN	8,694	10,737	(2,043)
SARM	Ostarine™ Cancer cachexia	7,056	6,723	333
	GTx-838	1,747	—	1,747
Other research and development		11,589	7,991	3,598
Total research and development expenses		\$ 38,508	\$ 33,897	\$ 4,611

**General and Administrative Expenses.** General and administrative expenses increased 18.4% to \$13.5 million for the year ended December 31, 2007 from \$11.4 million for the year ended December 31, 2006. The increase of approximately \$2.1 million was primarily the result of increased personnel related expenses of approximately \$1.0 million, an increase in marketing and promotional expenses of \$757,000 and an increase in intellectual property and other legal expenses of \$730,000.

**Interest Income.** Interest income increased to \$5.1 million for the year ended December 31, 2007 from \$3.0 million for the year ended December 31, 2006. The increase of approximately \$2.1 million was attributable to higher average interest rates in addition to higher average cash and cash equivalents balances during the year ended December 31, 2007, as compared to the prior year.

### Comparison of Years Ended December 31, 2006 and December 31, 2005

**Revenues.** Revenues for the year ended December 31, 2006 were \$7.5 million as compared to \$3.8 million for the same period of 2005. Revenues for the year ended December 31, 2006 included net sales of FARESTON® of \$1.4 million while cost of product sales was \$773,000. Collaboration income for the year ended December 31, 2006 was \$6.1 million, which consisted of \$4.3 million from Ortho Biotech and \$1.8 million from Ipsen. During the year ended December 31, 2005, FARESTON® net sales were \$2.4 million while cost of product sales was \$1.6 million. Revenues for the year ended December 31, 2005 also included collaboration income of \$1.3 million from Ortho Biotech.

**Research and Development Expenses.** Research and development expenses increased 9.7% to \$33.9 million for the year ended December 31, 2006 from \$30.9 million for the year ended December 31, 2005. The following table identifies the research and development expenses for certain of our product candidates, as well as research and development expenses pertaining to our other research and development efforts for each of the periods presented.

Program	Product Candidate/ Indication	Year Ended December 31,		Increase (Decrease)
		2006	2005	
		(in thousands)		
SERM	ACAPODENE® 80 mg Multiple serious side effects of ADT	\$ 8,446	\$ 11,720	\$ (3,274)
	ACAPODENE® 20 mg Prevention of prostate cancer in high risk men with high grade PIN	10,737	7,615	3,122
SARM	Ostarine™ Cancer cachexia	6,723	4,750	1,973
Other research and development		7,991	6,838	1,153
Total research and development expenses		\$ 33,897	\$ 30,923	\$ 2,974

**General and Administrative Expenses.** General and administrative expenses increased 16% to \$11.4 million for the year ended December 31, 2006 from \$9.8 million for the year ended December 31, 2005. The increase of approximately \$1.6 million was primarily due to an increase in personnel related expenses, share-based compensation expense as a result of the adoption of SFAS No. 123R effective January 1, 2006 and foreign currency transactions losses related to our Ipsen collaboration.

**Interest Income.** Interest income increased to approximately \$3.0 million for the year ended December 31, 2006 from \$1.7 million for the year ended December 31, 2005. The increase was the result of higher average interest rates in addition to higher average cash and cash equivalents balances during the year ended December 31, 2006, as compared to the prior year.



## Liquidity and Capital Resources

Through December 31, 2007, we financed our operations and internal growth through private placements of preferred stock and common stock, the proceeds of our public offerings of our common stock, and proceeds from our collaborations. We have incurred significant losses since our inception in 1997 as we have devoted substantially all of our resources to research and development, including our clinical trials. As of December 31, 2007, we had an accumulated deficit of \$270.1 million, of which \$96.3 million related to non-cash dividends and adjustments to the preferred stock redemption value. Our accumulated deficit resulted primarily from:

- Our research and development activities associated with:
  - ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT, including two Phase II clinical trials and a pivotal Phase III clinical trial;
  - ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, including our Phase IIb clinical trial and an ongoing pivotal Phase III clinical trial;
  - Preclinical and clinical development of Ostarine™, GTx-838, and our other SARM compounds, which are being developed for the treatment of muscle wasting and/or bone loss;
- General and administrative expenses; and
- Non-cash dividends and adjustments to the preferred stock redemption value of \$96.3 million related to our cumulative redeemable convertible preferred stock.

We expect to continue to incur net losses over the next several years as we continue our clinical development and research and development activities, apply for regulatory approvals, expand our sales and marketing capabilities and grow our operations.

At December 31, 2007, we had cash, cash equivalents and short-term investments of \$110.0 million, compared to \$119.6 million at December 31, 2006 and \$74.0 million at December 31, 2005. On October 17, 2005, we completed an underwritten public offering of 6,325,000 shares of common stock at an offering price to the public of \$7.80 per share resulting in net proceeds of approximately \$45.7 million. On December 18, 2006, we completed a public offering of 3,799,600 shares of common stock at an offering price to the public of \$16.00 per share resulting in net proceeds of approximately \$57.4 million. On December 18, 2007, we completed a private placement of 1,285,347 shares of common stock to Merck and received proceeds of approximately \$30.0 million.

Net cash used in operating activities was \$37.6 million, \$11.5 million and \$34.8 million for the years ended December 31, 2007, 2006 and 2005, respectively. The use of cash in all periods resulted primarily from funding our net losses. Net cash used in operating activities for the year ended December 31, 2006 was reduced by the receipt of approximately \$27.1 million in connection with our collaboration with Ipsen. Cash requirements for operating activities are expected to increase in future periods, due in part to costs related to the continuation of two pivotal Phase III clinical trials for ACAPODENE® as well as the clinical and preclinical development of Ostarine™ and our other product candidates.

Net cash used in investing activities for the year ended December 31, 2007 was \$1.7 million and was primarily for the purchase of research and development equipment, office equipment, computer equipment and software and the purchase of intangible assets (license fees) of \$513,000. Net cash used in investing activities for 2006 was \$578,000 and was primarily for the purchase of research and development equipment, computer equipment and software. Net cash used in investing activities in 2005 was \$1.4 million and was primarily for the purchase of research and development equipment, leasehold improvements, office and computer equipment, software and furniture and fixtures. We currently expect to make expenditures for property and equipment of up to \$3.3 million for the year ended December 31, 2008.

Net cash provided by financing activities was \$20.0 million, \$57.6 million and \$45.7 million for the years ended December 31, 2007, 2006 and 2005, respectively. Net cash provided by financing activities for the year ended December 31, 2007 reflected the proceeds from our private placement of 1,285,347 shares of common stock to Merck on December 18, 2007 and proceeds of \$826,000 from the exercise of employee stock options. Net cash provided by financing activities for the year ended December 31, 2006 reflected net proceeds from our follow-on

public offering, which closed on December 18, 2006. Net cash provided by financing activities for the year ended December 31, 2005 reflected net proceeds from our follow-on offering which closed October 17, 2005.

We estimate that our current cash resources, including the \$40.0 million license fee we received from Merck in January 2008, interest on these funds and product revenue from the sale of FARESTON<sup>®</sup>, will be sufficient to meet our projected operating requirements through at least the first quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaborations with Ipsen and Merck, nor does it include any funding that we may receive under potential future collaboration arrangements with other pharmaceutical companies or potential future issuances and sales of our securities.

Our forecast of the period of time through which our financial resources will be adequate to support our projected operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed under Item 1A "Risk Factors" section of this annual report on Form 10-K. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials, other research and development activities and commercialization. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our and/or our collaborators' clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaborative arrangements with Merck and Ipsen;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Merck and Ipsen;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our collaborators may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, such as our arrangements with Merck and Ipsen, as well as through interest income earned on cash balances and short-term investments and revenues from the sale of FARESTON<sup>®</sup>. With the exception of payments that we may receive under our collaborations with Merck and Ipsen, we do not currently have any commitments for future external funding. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through

collaboration and licensing arrangements, such as our arrangements with Merck and Ipsen, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop on our own.

We have no long-term debt. At December 31, 2007, we had contractual obligations as follows:

	<u>Total</u>	<u>Payment Due by Period</u> <u>(in thousands)</u>			
		<u>Less than</u> <u>1 year</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>More than</u> <u>5 years</u>
Capital lease obligations	\$ 10	\$ 5	\$ 5	\$ —	\$ —
Operating lease obligations	2,198	1,141	1,057	—	—
Purchase obligations	280	280	—	—	—
Total	<u>\$ 2,488</u>	<u>\$ 1,426</u>	<u>\$ 1,062</u>	<u>\$ —</u>	<u>\$ —</u>

Our long-term commitments under the operating leases shown above consist of payments relating to a lease for laboratory and office space at 3 North Dunlap Street, Memphis, Tennessee and a lease for office space at 50 South Third Street, Memphis, Tennessee. Our lease agreement for the premises located at 3 North Dunlap Street expires on December 31, 2008, unless we exercise options to extend the lease for an additional two years. Our lease agreement for the premises located at 50 South Third Street expires on April 30, 2015, but we have the ability to cancel the lease beginning on December 31, 2010. The table above excludes contingent payments under the license agreements to which we are a party.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in highly liquid money market funds. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We do not use derivative financial instruments in our investment portfolio. The effect of a hypothetical decrease of ten percent in the average yield earned on our cash equivalents and short-term investments would have resulted in a decrease in our interest income of approximately \$500,000 for the year ended December 31, 2007.

Our exposure to credit risk relates to our investment in money market funds and in Bank of America Corporation's Columbia Strategic Cash Portfolio (the "Fund"). In December 2007, Columbia Management Group, LLC, the Fund's manager, determined that the assets of the Fund had declined in fair value and the Fund would no longer seek to maintain a net asset value ("NAV") of one dollar per share. As a result, the Fund's NAV began to fluctuate based on changes in the market values of the assets owned by the Fund. The Fund ceased accepting orders for new shares and began an orderly liquidation of Fund assets for distribution to its shareholders. At December 31, 2007, the Fund's NAV was \$0.9874 per share. For the year ended December 31, 2007, we recognized a loss on our investment in the Fund of approximately \$137,000. If the current credit environment continues to deteriorate, our investments in money market funds could become impaired and our investment in the Columbia Strategic Cash Portfolio could suffer additional losses, which would adversely impact our financial results.

We operate primarily in the United States. However, some of our clinical trial sites are located in Canada, Germany, Ireland, Mexico and the United Kingdom which requires us to make payments for certain clinical trial services in foreign currencies. In accordance with the terms of our collaboration and license agreement with Ipsen, Ipsen is required to pay us €1.0 million as additional license fees over the next two years. We are also entitled to receive from Ipsen up to €39.0 million in milestone payments subject to the successful development and launch of ACAPODENE® in certain countries of the European Territory. Ipsen's obligation to make payments to us in Euros exposes us to potential foreign currency transaction losses. Our exposure to foreign currency rate fluctuations will increase if and to the extent we are able to commercialize ACAPODENE® because we are obligated to pay Orion Corporation, our supplier of ACAPODENE® and FARESTON®, in Euros. However, such exposure is not expected to be material. We do not currently use derivative financial instruments to mitigate this exposure.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Our financial statements and the reports of our independent registered public accounting firm are included in this Annual Report on Form 10-K beginning on page F-1. The index to these reports and our financial statements is included in Part IV, Item 15 below.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosures.

We have carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on the evaluation of these disclosure controls and procedures, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective.

### **Management's Report on Internal Control over Financial Reporting**

We, as management of GTx, Inc., are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles. Any system of internal control, no matter how well designed, has inherent limitations, including the possibility that a control can be circumvented or overridden and misstatements due to error or fraud may occur and not be detected. Also, because of changes in conditions, internal control effectiveness may vary over time. Accordingly, even an effective system of internal control will provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007 using the criteria for effective internal control over financial reporting as described in "Internal Control – Integrated Framework," issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this evaluation, we concluded that, as of December 31, 2007, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm.

### **Attestation Report of the Independent Registered Public Accounting Firm**

Ernst & Young LLP, an independent registered public accounting firm, has issued an audit report on the effectiveness of our internal control over financial reporting, which report is included elsewhere herein.

## Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

On December 17, 2007, we entered into a sublease agreement (the “Sublease”) with ESS SUSA Holdings, LLC (“Landlord”) for the lease of premises containing approximately 30,748 square feet of office space (the “Leased Space”) located at 50 South Third Street, Memphis, Tennessee (the “Premises”). The term of the Sublease will continue through April 30, 2015, subject to our option to cancel the Sublease beginning December 31, 2010 upon six months prior written notice and subject to the early cancellation payments as indicated in the table below:

<u>Sublease Cancellation Date</u>	<u>Early Cancellation Payment</u>
12/31/2010	\$150,000
12/31/2011	\$75,000
12/31/2012	\$50,000
12/31/2013	\$50,000

Rent payments under the Sublease commenced on January 1, 2008. The monthly base rent during the term of the Sublease (the “Base Rent”) is as follows:

<u>Period</u>	<u>Base Rent<sup>1</sup></u>
1/1/2008-6/30/2008	\$17,936 per month
7/1/2008-12/31/2008	\$35,873 per month
1/1/2009-12/31/2009	\$37,154 per month
1/1/2010-12/31/2010	\$38,435 per month
1/1/2011-12/31/2011	\$40,997 per month
1/1/2012-12/31/2012	\$43,560 per month
1/1/2013-12/31/2013	\$44,841 per month
1/1/2014-4/30/2015	\$46,122 per month

<sup>1</sup> Base Rent under the Sublease is subject to certain upward operating expense adjustments allocable to the Leased Space.

Under the terms of the Sublease, the Landlord granted to us a right of first refusal to lease additional office space in the Premises. The Sublease also contains customary operating lease provisions and is subject to certain terms of the lease agreement between the lessor of the Premises and Landlord, as tenant thereunder. The foregoing is only a brief description of the material terms of the Sublease, does not purport to be a complete statement of the rights and obligations of the parties under the Sublease, and is qualified in its entirety by reference to the Sublease that is filed as Exhibit 10.46 this Annual Report on Form 10-K.

## PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file our definitive proxy statement for our 2008 Annual Meeting of Stockholders with the U.S. Securities and Exchange Commission pursuant to Regulation 14A (the “2008 Proxy Statement”) not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information included in the 2008 Proxy Statement is incorporated herein by reference.

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

(1) The information required by this Item concerning our directors and nominees for director, including information with respect to our audit committee and audit committee financial experts, may be found under the section entitled “Proposal No. 1 – Election of Directors” and “Additional Information About the Board of Directors” appearing in the 2008 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 may be found in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" appearing in the 2008 Proxy Statement. Such information is incorporated herein by reference.

(3) The information required by this Item concerning our executive officers is set forth in the section entitled "Executive Officers of Registrant" in Part I, Item 1 of this Form 10-K and is incorporated herein by reference.

(4) Our Board has adopted a Code of Business Conduct and Ethics applicable to all officers, directors and employees as well as Guidelines on Governance Issues. These documents are available on our website ([www.gtxinc.com](http://www.gtxinc.com)) under "About GTx" at "Corporate Governance." We will provide a copy of these documents to any person, without charge, upon request, by writing to us at GTx, Inc. Director, Corporate Communications and Financial Analysis, 3 North Dunlap Street, Memphis, Tennessee 38163. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of the Code of Business Conduct and Ethics by posting such information on our website at the address and the locations specified above.

#### **ITEM 11. EXECUTIVE COMPENSATION**

(1) The information required by this Item concerning director and executive compensation is incorporated herein by reference to the information from the 2008 Proxy Statement under the sections entitled "Compensation Discussion and Analysis," "Executive Compensation" and "Director Compensation."

(2) The information required by this Item concerning Compensation Committee interlocks and insider participation is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Compensation Committee Interlocks and Insider Participation."

(3) The information required by this Item concerning our Compensation Committee's review and discussion of our Compensation Discussion and Analysis is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Compensation Committee Report."

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

(1) The information required by this Item with respect to security ownership of certain beneficial owners and management is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Security Ownership of Certain Beneficial Owners and Management."

(2) The information required by this Item with respect to securities authorized for issuance under our equity compensation plans is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Equity Compensation Plan Information."

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

(1) The information required by this Item concerning related party transactions is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Certain Relationships and Related Party Transactions."

(2) The information required by this Item concerning director independence is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Additional Information about the Board of Directors – Director Independence."

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Proposal No. 2 – Ratification of Appointment of Independent Registered Public Accounting Firm."

## PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

### (a)(1) Index to Financial Statements

<u>Page</u>	<u>Description</u>
F-2	Management's Report on Internal Control Over Financial Reporting
F-3	Reports of Independent Registered Public Accounting Firm
F-5	Balance Sheets at December 31, 2007 and 2006
F-6	Statements of Operations for the Years Ended December 31, 2007, 2006 and 2005
F-7	Statements of Stockholders' Equity for the Years Ended December 31, 2007, 2006 and 2005
F-8	Statements of Cash Flows for the Years Ended December 31, 2007, 2006 and 2005
F-9	Notes to Financial Statements

### (a)(2) Financial statement schedules are omitted as they are not applicable.

### (a)(3) See 15(b) below.

### (b) Exhibits

<u>Number</u>	<u>Description</u>
3.1	Restated Certificate of Incorporation of GTx, Inc. <sup>(1)</sup>
3.2	Amended and Restated Bylaws of GTx, Inc. <sup>(2)</sup>
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen of Common Stock Certificate <sup>(3)</sup>
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003 <sup>(3)</sup>
4.4*	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003 <sup>(3)</sup>
4.5	Consent, Waiver and Amendment between the Registrant and Oracle Partners, L.P., Oracle Investment Management, Inc. and Oracle Institutional Partners, L.P. dated November 29, 2007 <sup>(4)</sup>
4.6	Consent, Waiver and Amendment between Registrant and J. R. Hyde, III and Pittco Associates, L.P. dated December 3, 2007 <sup>(4)</sup>
4.7	Registration Rights Agreement between Registrant and Merck & Co., Inc. dated December 18, 2007 <sup>(5)</sup>
10.1*	Genotherapeutics, Inc. 1999 Stock Option Plan <sup>(3)</sup>
10.2*	GTx, Inc. 2000 Stock Option Plan <sup>(3)</sup>
10.3*	GTx, Inc. 2001 Stock Option Plan <sup>(3)</sup>
10.4*	GTx, Inc. 2002 Stock Option Plan <sup>(3)</sup>
10.5*	2004 Equity Incentive Plan and Form of Stock Option Agreement <sup>(3)</sup>
10.6	Reserved
10.7*	Directors' Deferred Compensation Plan <sup>(6)</sup>
10.8*	Employment Agreement dated October 1, 2003, between Registrant and Mitchell S. Steiner, M.D. <sup>(3)</sup>
10.9*	Employment Agreement dated October 1, 2003, between Registrant and Marc S. Hanover <sup>(3)</sup>
10.10*	Employment Agreement dated October 1, 2003, between Registrant and Mark E. Mosteller <sup>(3)</sup>
10.11*	Employment Agreement dated October 1, 2003, between Registrant and Henry P. Doggrell <sup>(3)</sup>
10.12*	Form of Indemnification Agreement <sup>(3)</sup>
10.13	Lease Agreement, dated March 7, 2001, between The University of Tennessee and TriStar Enterprises, Inc. <sup>(3)</sup>
10.14	Sublease Agreement dated October 1, 2000, as amended, between Registrant and TriStar Enterprises, Inc. <sup>(3)</sup>

<u>Number</u>	<u>Description</u>
10.15†	Amended and Restated License and Supply Agreement dated October 22, 2001, between Registrant and Orion Corporation <sup>(7)</sup>
10.16†	Amendment No. 1 to the License and Supply Agreement dated March 5, 2003, between Registrant and Orion Corporation <sup>(3)</sup>
10.20	Reserved
10.21	Reserved
10.22	Reserved
10.23†	Amendment No. 2 to the License and Supply Agreement dated December 29, 2003, between Registrant and Orion Corporation <sup>(3)</sup>
10.24††	Purchase Agreement dated December 13, 2004, between Registrant and Orion Corporation <sup>(8)</sup>
10.25††	Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation <sup>(9)</sup>
10.26	Sublease Agreement dated April 1, 2005, as amended, between Registrant and TriStar Enterprises, Inc. <sup>(10)</sup>
10.27*	Employment Agreement dated April 12, 2007, between Registrant and James T. Dalton <sup>(11)</sup>
10.28*	2007 Compensation Information for Registrant's Executive Officers <sup>(12)</sup>
10.29*	Employment Agreement dated August 26, 2005, between Registrant and K. Gary Barnette <sup>(13)</sup>
10.30*	Employment Agreement dated August 26, 2005, between Registrant and Gregory A. Deener <sup>(14)</sup>
10.31*	Amended and Restated 2004 Non-Employee Directors' Stock Option Plan <sup>(15)</sup>
10.32††	Amendment dated May 23, 2006 to the Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation <sup>(16)</sup>
10.33††	Amendment dated June 30, 2006 to the Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation <sup>(17)</sup>
10.34*	Form of Stock Option Agreement under the Amended and Restated 2004 Non-Employee Directors' Stock Option Plan <sup>(18)</sup>
10.35††	Partial Assignment Agreement among Registrant, Orion Corporation and Ipsen Limited dated September 7, 2006 <sup>(19)</sup>
10.36†	Collaboration and License Agreement between Registrant and Ipsen Limited dated September 7, 2006 <sup>(20)</sup>
10.37*	Executive Bonus Compensation Plan <sup>(21)</sup>
10.38*	Employment Agreement dated April 12, 2007, between Registrant and Ronald A. Morton, Jr., M.D. <sup>(f1)</sup>
10.39*	Employment Agreement dated May 15, 2007, between Registrant and Jeff G. Hesselberg <sup>(11)</sup>
10.40†	Consolidated, Amended, and Restated License Agreement dated July 24, 2007, between Registrant and University of Tennessee Research Foundation <sup>(6)</sup>
10.41†	Amended and Restated License Agreement dated September 24, 2007, between Registrant and University of Tennessee Research Foundation <sup>(6)</sup>
10.42	Stock Purchase Agreement, dated November 5, 2007, between the Registrant and Merck & Co., Inc. <sup>(22)</sup>
10.43†††	Exclusive License and Collaboration Agreement between the Registrant and Merck & Co., Inc. dated November 5, 2007
10.44*	2008 Compensation Information for Registrant's Executive Officers
10.45*	Non-Employee Director Compensation Arrangements
10.46	Sublease Agreement, dated December 17, 2007 by and between the Registrant and ESS SUSA Holdings, LLC
12.1	Statement of Computation of Deficiency of Earnings Available to Cover Fixed Charges
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature pages hereto)
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certification of Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) <sup>(23)</sup>
32.2	Certification of Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) <sup>(23)</sup>

† Confidential treatment granted. The redacted portions have been filed separately with the SEC as required by Rule 406 of Regulation C.

†† Confidential treatment extension requested. The redacted portions have been filed separately with the SEC as required by Rule 406 of Regulation C.

††† Confidential treatment requested. The redacted portions have been filed separately with the SEC as required



by Rule 406 of Regulation C.

\* Indicates a management contract or compensation plan or arrangement.

- (1) Filed as Exhibit 4.1 to the Registrant's registration statement on Form S-3 (File No. 333-127175), filed with the SEC on August 4, 2005, and incorporated herein by reference.
- (2) Filed as the like numbered Exhibit to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on July 26, 2007, as amended, and incorporated herein by reference.
- (3) Filed as the like numbered Exhibit to the Registrant's registration statement on Form S-1 (File No. 333-109700), filed with the SEC on October 15, 2003, as amended, and incorporated herein by reference.
- (4) Filed as the like numbered Exhibit to the Registrant's registration statement on Form S-3 (File No. 333-148321), filed with the SEC on December 26, 2007, and incorporated herein by reference.
- (5) Filed as the like numbered Exhibit to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the Securities and Exchange Commission on December 18, 2007, and incorporated herein by reference.
- (6) Filed as the like numbered Exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on November 9, 2007, and incorporated herein by reference.
- (7) Filed as the like numbered Exhibit to the Registrant's Annual Report on Form 10-K (File No. 000-50549), filed with the SEC on March 9, 2007, and incorporated herein by reference.
- (8) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A (File No. 000-50549), filed with the SEC on March 7, 2005, and incorporated herein by reference.
- (9) Filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K/A (File No. 000-50549), filed with the SEC on March 7, 2005, and incorporated herein by reference.
- (10) Filed as Exhibit 10.27 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on July 27, 2005, and incorporated herein by reference.
- (11) Filed as the like numbered Exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 1, 2007, and incorporated herein by reference.
- (12) Filed as Exhibit 10.28 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on May 7, 2007, and incorporated herein by reference.
- (13) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on September 8, 2005, and incorporated herein by reference.
- (14) Filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on September 8, 2005 and incorporated herein by reference.
- (15) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on April 27, 2006, and incorporated herein by reference.
- (16) Filed as Exhibit 10.33 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 9, 2006, and incorporated herein by reference.
- (17) Filed as Exhibit 10.34 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 9, 2006, and incorporated herein by reference.
- (18) Filed as Exhibit 10.35 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 9, 2006, and incorporated herein by reference.
- (19) Filed as Exhibit 10.36 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on November 3, 2006, and incorporated herein by reference.
- (20) Filed as Exhibit 10.37 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the

SEC on November 3, 2006, and incorporated herein by reference.

- <sup>(21)</sup> Filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on November 3, 2006, and incorporated herein by reference.
- <sup>(22)</sup> Filed as Exhibit 10.42 to the Registrant's current report on Form 8-K (File No. 000-50549), filed with the SEC on November 6, 2007, and incorporated herein by reference.
- <sup>(23)</sup> This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GTx, Inc.

By /s/ Mitchell S. Steiner  
Mitchell S. Steiner, M.D., F.A.C.S.  
 Chief Executive Officer, Vice Chairman and Director

Date: March 11, 2008

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Mitchell S. Steiner and Mark E. Mosteller, and each of them, acting individually, as his attorney-in-fact, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

		<u>Date</u>
<u>/s/ J. R. Hyde, III</u> J. R. Hyde, III	Chairman of the Board of Directors	March 11, 2008
<u>/s/ Mitchell S. Steiner</u> Mitchell S. Steiner, M.D., F.A.C.S.	Chief Executive Officer, Vice Chairman and Director	March 11, 2008
<u>/s/ Mark E. Mosteller</u> Mark E. Mosteller, CPA	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 11, 2008
<u>/s/ Marc S. Hanover</u> Marc S. Hanover	President, Chief Operating Officer and Director	March 11, 2008
<u>/s/ Andrew M. Clarkson</u> Andrew M. Clarkson	Director	March 11, 2008
<u>/s/ J. Kenneth Glass</u> J. Kenneth Glass	Director	March 11, 2008
<u>/s/ Robert W. Karr</u> Robert W. Karr, M.D.	Director	March 11, 2008
<u>/s/ Rosemary Mazanet</u> Rosemary Mazanet, M.D., Ph.D.	Director	March 11, 2008

<u>/s/ John H. Pontius</u> John H. Pontius	Director	March 11, 2008
<u>/s/ Timothy R. G. Sear</u> Timothy R. G. Sear	Director	March 11, 2008
<u>/s/ Michael G. Carter</u> Michael G. Carter, M. D.	Director	March 11, 2008

**GTx, Inc.**

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## MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

We, as management of GTX, Inc., are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles. Any system of internal control, no matter how well designed, has inherent limitations, including the possibility that a control can be circumvented or overridden and misstatements due to error or fraud may occur and not be detected. Also, because of changes in conditions, internal control effectiveness may vary over time. Accordingly, even an effective system of internal control will provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007 using the criteria for effective internal control over financial reporting as described in "Internal Control – Integrated Framework," issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this evaluation, we concluded that, as of December 31, 2007, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm.

/s/ Mitchell S. Steiner  
**Mitchell S. Steiner, M.D., F.A.C.S.**  
Vice Chairman and  
Chief Executive Officer

/s/ Mark E. Mosteller  
**Mark E. Mosteller, CPA**  
Vice President, Chief Financial Officer  
and Treasurer

Memphis, Tennessee  
March 6, 2008

## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of GTx, Inc.

We have audited GTx, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). GTx Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, GTx, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the accompanying balance sheets as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007 of GTx, Inc. and our report dated March 6, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee  
March 6, 2008

## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of GTx, Inc.

We have audited the accompanying balance sheets of GTx, Inc. as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of GTx, Inc. at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, to account for stock based compensation.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of GTx, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 6, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee  
March 6, 2008



**GTx, Inc.**  
**BALANCE SHEETS**  
(in thousands, except share data)

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 100,178	\$ 119,550
Short-term investments	9,810	-
Accounts receivable, net	117	61
Inventory	78	207
Receivable from collaboration partners	40,719	660
Prepaid expenses and other current assets	1,362	1,222
Total current assets	152,264	121,700
Property and equipment, net	2,308	1,936
Intangible assets, net	4,430	4,226
Other assets	728	1,393
Total assets	<u>\$ 159,730</u>	<u>\$ 129,255</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,614	\$ 1,336
Accrued expenses	6,784	3,149
Deferred revenue – current portion	10,934	5,852
Total current liabilities	19,332	10,337
Deferred revenue, less current portion	61,245	21,554
Capital lease obligation	10	15
Other long-term liability	226	300
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized; 36,216,263 shares issued and outstanding at December 31, 2007 and 34,822,362 shares issued and outstanding at December 31, 2006	36	35
Additional paid-in capital	349,019	326,793
Accumulated deficit	(270,138)	(229,779)
Total stockholders' equity	78,917	97,049
Total liabilities and stockholders' equity	<u>\$ 159,730</u>	<u>\$ 129,255</u>

The accompanying notes are an integral part of these financial statements.

**GTx, Inc.**  
**STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
Revenues:			
Product sales, net	\$ 1,076	\$ 1,357	\$ 2,445
Collaboration revenue	6,050	6,148	1,337
Total revenues	<u>7,126</u>	<u>7,505</u>	<u>3,782</u>
Costs and expenses:			
Cost of product sales	621	773	1,573
Research and development expenses	38,508	33,897	30,923
General and administrative expenses	13,501	11,352	9,845
Total costs and expenses	<u>52,630</u>	<u>46,022</u>	<u>42,341</u>
Loss from operations	(45,504)	(38,517)	(38,559)
Interest income	5,145	3,007	1,720
Net loss	<u>\$ (40,359)</u>	<u>\$ (35,510)</u>	<u>\$ (36,839)</u>
Net loss per share:			
Basic and diluted	<u>\$ (1.16)</u>	<u>\$ (1.14)</u>	<u>\$ (1.42)</u>
Weighted average shares used in computing net loss per share:			
Basic and diluted	<u>34,940,151</u>	<u>31,150,035</u>	<u>25,982,478</u>

The accompanying notes are an integral part of these financial statements.

**GTx, Inc.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
**For the Years Ended December 31, 2007, 2006 and 2005**  
**(in thousands, except share and per share data)**

	Stockholders' Equity					
	Common Stock		Deferred Stock Compensation	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at January 1, 2005	24,664,716	\$ 25	\$ (2,701)	\$ 224,015	\$ (157,430)	\$ 63,909
Issuance of common stock	6,325,000	6	-	45,657	-	45,663
Amortization of stock-based compensation	-	-	487	-	-	487
Exercise of employee stock options	4,251	-	-	27	-	27
Forfeitures of stock-based compensation	-	-	489	(489)	-	-
Directors' deferred compensation	-	-	-	180	-	180
Share-based compensation related to the modification of employee stock options	-	-	-	152	-	152
Net loss and comprehensive loss	-	-	-	-	(36,839)	(36,839)
Balances at December 31, 2005	30,993,967	31	(1,725)	269,542	(194,269)	73,579
Issuance of common stock	3,799,600	4	-	57,422	-	57,426
Exercise of employee stock options	28,795	-	-	153	-	153
Directors' deferred compensation	-	-	-	140	-	140
Share-based compensation	-	-	-	1,261	-	1,261
Reversal of deferred stock compensation	-	-	1,725	(1,725)	-	-
Net loss and comprehensive loss	-	-	-	-	(35,510)	(35,510)
Balances at December 31, 2006	34,822,362	35	-	326,793	(229,779)	97,049
Issuance of common stock	1,285,347	1	-	19,176	-	19,177
Exercise of employee stock options	108,554	-	-	826	-	826
Directors' deferred compensation	-	-	-	183	-	183
Share-based compensation	-	-	-	2,041	-	2,041
Net loss and comprehensive loss	-	-	-	-	(40,359)	(40,359)
Balances at December 31, 2007	36,216,263	\$ 36	\$ -	\$ 349,019	\$ (270,138)	\$ 78,917

The accompanying notes are an integral part of these financial statements.

**GTx, Inc.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)

	Years Ended December 31,		
	2007	2006	2005
<b>Cash flows from operating activities:</b>			
Net loss	\$ (40,359)	\$ (35,510)	\$ (36,839)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,150	1,140	1,038
Share-based compensation	2,041	1,261	639
Directors' deferred compensation	183	140	180
Deferred revenue amortization	(6,050)	(6,148)	(1,337)
Foreign currency transaction (gain) loss	(140)	237	—
Loss on retirement of property and equipment	9	—	33
Changes in assets and liabilities:			
Short-term investments	(9,810)	—	—
Accounts receivable, net	(56)	92	(153)
Inventory	129	(72)	313
Receivable from collaboration partners	(39,372)	(2,146)	—
Prepaid expenses and other assets	(21)	419	(93)
Accounts payable	278	(71)	507
Accrued expenses and other long-term liability	3,561	(61)	893
Deferred revenue	50,823	29,259	—
Net cash used in operating activities	(37,634)	(11,460)	(34,819)
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(1,223)	(578)	(1,381)
Purchase of intangible assets	(513)	—	—
Net cash used in investing activities	(1,736)	(578)	(1,381)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock	19,177	57,426	45,663
Proceeds from exercise of employee stock options	826	153	27
Payments on capital lease obligation	(5)	(5)	(4)
Net cash provided by financing activities	19,998	57,574	45,686
Net increase (decrease) in cash and cash equivalents	(19,372)	45,536	9,486
Cash and cash equivalents, beginning of year	119,550	74,014	64,528
Cash and cash equivalents, end of year	\$ 100,178	\$ 119,550	\$ 74,014

The accompanying notes are an integral part of these financial statements.

**GTx, Inc.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

**1. Business and Basis of Presentation**

***Business***

GTx, Inc. ("GTx" or the "Company"), a Delaware corporation incorporated on September 24, 1997 and headquartered in Memphis, Tennessee, is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. GTx operates in one business segment.

GTx is developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator ("SERM") in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy ("ADT") for advanced prostate cancer and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia ("high grade PIN"). GTx has licensed to Ipsen Limited ("Ipsen") exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (collectively, the "European Territory") to develop and commercialize ACAPODENE® and other products containing toremifene for all indications which we have licensed from Orion Corporation ("Orion"). The Company has entered into an exclusive license and collaboration agreement with Merck & Co., Inc. ("Merck") establishing a global strategic collaboration for the discovery, development and commercialization of selective androgen receptor modulators ("SARMs"), including Ostarine™. GTx is currently evaluating Ostarine™ in a Phase II clinical trial for the treatment of muscle loss in patients with cancer, which is known as cancer cachexia.

**2. Significant Accounting Policies**

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual amounts and results could differ from those estimates.

***Cash and Cash Equivalents***

The Company considers highly liquid investments with initial maturities of three months or less to be cash equivalents.

***Short-term Investments***

Short-term investments consist of an investment in Bank of America Corporation's Columbia Strategic Cash Portfolio (the "Fund"). In December 2007, Columbia Management Group, LLC, the Fund's manager, determined that the assets of the Fund had declined in fair value and the Fund would no longer seek to maintain a net asset value ("NAV") of one dollar per share. As a result, the Fund's NAV began to fluctuate based on changes in the market values of the assets owned by the Fund. The Fund ceased accepting orders for new shares and began an orderly liquidation of Fund assets for distribution to its shareholders. The Company, therefore, reclassified this investment to short-term investments from cash equivalents. At December 31, 2007, the Fund's NAV was \$0.9874 per share. For the year ended December 31, 2007, the Company recognized a loss on its investment in the Fund of approximately \$137.

The Company has classified this investment as trading, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Accordingly, this investment is carried at fair value and all unrealized gains and losses are included in the statement of operations.

**GTx, Inc.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

***Inventory***

Inventory consists of FARESTON® tablets that are manufactured by Orion and delivered to the Company as finished goods. Inventory is stated at the lower of cost (first-in, first-out method) or market.

***Property and Equipment***

Property and equipment is stated at cost. Amortization of leasehold improvements is recognized over the shorter of the estimated useful life of the leasehold improvement or the lease term. Depreciation is computed using the straight-line method over the estimated useful lives as follows:

Laboratory and office equipment	3 to 5 years
Leasehold improvements	3 to 6 years
Furniture and fixtures	5 years
Computer equipment and software	3 years

***Intangible Assets***

The Company accounts for its intangible assets in accordance with SFAS No.142, *Goodwill and Other Intangible Assets*, which requires that purchased intangible assets with finite lives be amortized over their estimated economic lives. The Company's intangible assets consist of license fees and represent the value of each license acquired by the Company pursuant to the agreements described in Note 6. The license fees are being amortized on a straight-line basis over the respective terms of the agreements.

***Impairment of Long-Lived Assets***

In accordance with SFAS No.144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets to be Disposed of*, the Company reviews long-lived assets for impairment whenever events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. An impairment loss would be recognized when estimated future cash flows is less than the carrying amount. The cash flow estimates would be based on management's best estimates, using appropriate and customary assumptions and projections at the time.

***Fair Value of Financial Instruments***

The carrying amounts of the Company's financial instruments, which include cash, cash equivalents, short-term investments, accounts receivable and accounts payable approximate their fair values.

***Concentration of Risk***

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, short-term investments and accounts receivable. The Company has established guidelines relating to diversification and maturities of its cash equivalents and short-term investments which are designed to manage risk. The Company's cash equivalents consist of bank deposits, certificates of deposit and money market funds. Bank deposits may at times be in excess of FDIC insurance limits. The Company's short-term investments consist of an investment in Bank of America Corporation's Columbia Strategic Cash Portfolio as discussed in *Short-term Investments* in Note 2.

**GTx, Inc.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

Three wholesale drug distributors individually comprised 51%, 35% and 8%, respectively, of the Company's accounts receivable as of December 31, 2007. These three distributors represented 33%, 38% and 22%, respectively, of the Company's gross product sales for the year ended December 31, 2007.

***Revenue Recognition***

The Company recognizes net product sales revenue from the sale of FARESTON<sup>®</sup> less deductions for estimated sales discounts and sales returns. Revenue from product sales is recognized when the goods are shipped and title and risk of loss pass to the customer and the other criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104 (together, "SAB No. 104") and SFAS No. 48, *Revenue Recognition When Right of Return Exists*, are satisfied. The Company accounts for rebates to certain governmental agencies as a reduction of product sales. The Company allows customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. The Company estimates an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At December 31, 2007 and 2006, the Company's accrual for product returns was \$324 and \$415, respectively. If actual future results are different than the Company's estimates, the Company may need to adjust its estimated accrual for product returns, which could have a material effect on results of operations in the period of the adjustment.

Collaboration revenue consists of non-refundable upfront payments and license fees associated with the Company's collaboration and license agreements discussed in Note 8. The Company recognizes this revenue in accordance with SAB No. 104, Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21") and EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* ("EITF 99-19"). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. The Company analyzes agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and performance obligations such as joint steering committee participation and research and development activities, can be separated or whether all of the deliverables must be accounted for as a single unit of accounting in accordance with EITF 00-21. For these arrangements, the Company generally is not able to identify evidence of fair value for the undelivered elements and therefore recognizes any consideration for a single unit of accounting in the same manner as revenue is recognized for the final deliverable, which is generally ratable over the performance period. The performance period is estimated at the inception of the agreement and is reevaluated at each reporting period. Cost reimbursements for research and development activities are recognized as collaboration revenue if the provisions of EITF 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured. Revenues from milestone payments for which the Company has no continuing performance obligations are recognized upon achievement of the performance milestone, as defined in the related agreement, provided the milestone is substantive and a culmination of the earnings process has occurred. Performance obligations typically consist of significant milestones in the development life cycle of the related products and technology, such as initiation of clinical trials, filing for approval with regulatory agencies and approvals by regulatory agencies.

***Research and Development Costs***

The Company expenses research and development costs in the period in which they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research and clinical trials on behalf of the Company.

***Patent Costs***

The Company expenses patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in the Company's statements of operations.

**GTx, Inc.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

***Income Taxes***

The Company accounts for deferred taxes by recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, at December 31, 2007 and 2006, net of the valuation allowance, the net deferred tax assets were reduced to zero.

***Stock Options***

The Company has stock option plans that provide for the purchase of the Company's common stock by certain of its employees and directors. Effective January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment* ("SFAS 123R") and began recognizing compensation expense for its share-based payments based on the fair value of the awards. See Note 3 for further discussion.

***Deferred Stock Compensation***

In anticipation of the Company's initial public offering on February 6, 2004, the Company determined that, for financial reporting purposes, the estimated value of its common stock was in excess of the exercise price for stock options issued to employees from June 30, 2003 to December 31, 2003. Accordingly, the Company recorded non-cash deferred stock-based compensation of \$4,055, and amortized the related expense on a straight-line basis over the estimated service period, which was generally five years. The Company recorded amortization of deferred stock compensation of \$487 for year ended December 31, 2005. At December 31, 2005, the Company had approximately \$1,725 of deferred stock-based compensation to be amortized over the remaining vesting periods of the related stock options. At January 1, 2006, upon adoption of SFAS 123R, the unamortized balance was reduced to zero with an offsetting adjustment to additional paid-in capital.

***Basic and Diluted Net Loss Per Share***

The Company computes net loss per share according to SFAS No. 128, *Earnings per Share*, which requires disclosure of basic and diluted earnings (loss) per share.

Basic net loss per share is calculated based on the weighted average number of common shares outstanding during the period. Diluted net loss per share gives effect to the dilutive potential of common stock consisting of stock options.



**GTx, Inc.**  
**NOTES TO FINANCIAL STATEMENTS**  
(in thousands, except share and per share data)

The following table sets forth the computation of the Company's basic and diluted net loss per share for the years ended December 31, 2007, 2006 and 2005:

	Years Ended December 31,		
	2007	2006	2005
<b>Basic and diluted net loss per share</b>			
Numerator:			
Net loss	\$ (40,359)	\$ (35,510)	\$ (36,839)
Denominator:			
Common stock outstanding at beginning of period	34,822,362	30,993,967	24,664,716
Issuance of common stock on a weighted average basis	49,301	145,738	1,316,986
Exercise of employee stock options on a weighted average basis	68,488	10,330	776
Weighted average shares used in computing basic and diluted net loss per share	34,940,151 <sup>(1)</sup>	31,150,035 <sup>(2)</sup>	25,982,478 <sup>(3)</sup>
Basic and diluted net loss per share	\$ (1.16)	\$ (1.14)	\$ (1.42)

(1) The weighted average shares used in computing basic and diluted net loss per share for the year ended December 31, 2007 included 49,301 shares, which represents the weighted average effect during the period of the Company's issuance of 1,285,347 shares of common stock to Merck on December 18, 2007. At December 31, 2007, the Company had outstanding 36,216,263 shares of common stock.

(2) The weighted average shares used in computing basic and diluted net loss per share for the year ended December 31, 2006 included 145,738 shares, which represents the weighted average effect during the period of the Company's issuance of 3,799,600 shares of common stock on December 18, 2006.

(3) The weighted average shares used in computing basic and diluted net loss per share for the year ended December 31, 2005 included 1,316,986 shares, which represents the weighted average effect during the period of the Company's issuance of 6,325,000 shares of common stock on October 17, 2005.

Weighted average options outstanding to purchase shares of common stock of 1,835,743, 1,462,842, and 1,244,232 were excluded from the calculation of diluted net loss per share for the years ended December 31, 2007, 2006 and 2005, respectively, as inclusion of the options would have an anti-dilutive effect on the net loss per share for the periods.

### ***Comprehensive Loss***

The Company has adopted the provisions of SFAS No. 130, *Comprehensive Income*. SFAS 130 establishes standards for the reporting and display of comprehensive income and its components for general purpose financial statements. For all periods presented, there were no differences between net loss and comprehensive loss.

### ***Reclassification***

The prior period computer software balance of \$488 has been reclassified from intangible assets to property and equipment in order to conform to the current period presentation. In addition, the 2006 and 2005 computer software purchases of \$240 and \$446, respectively, as reported in the statements of cash flows for the respective periods, have been reclassified from purchase of intangible assets to purchase of property and equipment.

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***Recent Accounting Pronouncements***

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109* ("FIN 48"), which clarifies the accounting for uncertainty in tax positions. FIN 48 requires the recognition of the impact of a tax position in the financial statements if that position is more likely than not of being sustained on audit based on the technical merits of the position. The provisions of FIN 48 were effective as of January 1, 2007. The adoption of the standard had no effect on the Company's financial condition or results of operations.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The FASB has deferred the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. The Company does not expect the adoption of SFAS 157 will have a material impact on its financial position or results of operations.

In June 2007, the Emerging Issues Task Force issued EITF Issue No. 07-03, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development* ("EITF 07-03"). EITF 07-03 concludes that nonrefundable advance payments for future research and development activities should be deferred and capitalized and recognized as expense as the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. The Company does not expect the adoption of EITF 07-03 will have a material impact on its financial position or results of operations.

In November 2007, the Emerging Issues Task Force issued EITF Issue No. 07-01, *Accounting for Collaborative Arrangements* ("EITF 07-01"). EITF 07-01 concludes that the equity method of accounting cannot be applied to collaborative arrangement activities that are not conducted within a separate legal entity. Instead, the revenues and costs incurred with third parties in connection with the collaborative arrangement should be presented gross or net by the collaborators based on the criteria in EITF 99-19, and other applicable accounting literature. EITF 07-01 is effective for years beginning after December 15, 2008. The Company does not expect the adoption of EITF 07-01 will have a material impact on its financial position or results of operations.

**3. Share-Based Compensation**

Effective January 1, 2006, the Company adopted SFAS 123R and began recognizing compensation expense for its share-based payments based on the fair value of the awards. Share-based payments include stock option grants under the Company's stock option plans. Prior to January 1, 2006, the Company accounted for share-based compensation expense using the intrinsic value recognition method prescribed by Accounting Principles Board Opinion ("APB") No. 25, *Accounting for Stock Issued to Employees* ("APB 25") and SFAS No. 123, *Accounting for Share-based Compensation* ("SFAS 123").

The Company grants options to purchase common stock to certain employees and directors under various plans at prices equal to the market value of the stock on the dates the options are granted. The options have a term of ten years from the grant date and vest three years from the grant date for director options and in periods up to five years from the grant date for employee options. Employees generally have 90 days after the employment relationship ends to exercise all vested options except in the case of retirement, permanent disability or death, where exercise periods are generally longer. The Company issues new shares of common stock upon the exercise of options. The fair value of each option grant is separately estimated for each vesting date. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the award and each vesting date. The Company estimates the fair value of certain stock option awards as of the date of the grant by applying the Black-Scholes-Merton option pricing valuation model. The application of this valuation model involves assumptions that are judgmental and highly sensitive in the determination of compensation expense.

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Total share-based compensation expense for the year ended December 31, 2007 was \$2,224, of which \$1,047 and \$1,177 were recorded in the statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the year ended December 31, 2006 was \$1,401, of which \$540 and \$861 were recorded in the statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the year ended December 31, 2005 was \$819. Share-based compensation expense for the years ended December 31, 2007, 2006 and 2005 included share-based compensation expense related to deferred compensation arrangements for the Company's directors of \$183, \$140 and \$180, respectively.

Since the Company adopted SFAS 123R under the modified prospective and the prospective transition methods, results from periods prior to 2006 have not been restated. On the date of adoption of SFAS 123R, the unamortized balance of deferred stock compensation of \$1,725 was reduced to zero with an offsetting adjustment to additional paid-in capital (see Note 2). SFAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required prior to the adoption of SFAS 123R. The impact of adopting SFAS 123R on future results will depend on, among other things, levels of share-based options granted in the future, actual forfeiture rates and the timing of option exercises.

The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No.123 to options granted under the Company's stock option plans in 2005.

	<b><u>Year Ended December 31, 2005</u></b>
Net loss as reported	\$ (36,839)
Add: Share-based compensation expense included in reported net loss	819
Deduct: Share-based compensation expense determined under the fair value based method	<u>(2,034)</u>
Pro forma net loss	<u>\$ (38,054)</u>
Net loss per share:	
Basic – as reported	<u>\$ (1.42)</u>
Basic – pro forma	<u>\$ (1.46)</u>
Diluted – as reported	<u>\$ (1.42)</u>
Diluted – pro forma	<u>\$ (1.46)</u>

For the years ended December 31, 2007, 2006 and 2005, the weighted average grant date fair value per share of options granted was \$10.41, \$5.67 and \$6.23, respectively. The weighted average for key assumptions used in determining the fair value of options granted in 2007, 2006 and 2005 and a summary of the methodology applied to develop each assumption are as follows:

	<b><u>Years Ended December 31,</u></b>		
	<b><u>2007</u></b>	<b><u>2006</u></b>	<b><u>2005</u></b>
Expected price volatility	50.6%	70.3%	61.6%
Risk-free interest rate	4.6%	4.6%	4.0%
Weighted average expected life in years	6.9 years	6.0 years	5.7 years
Dividend yield	0%	0%	0%
Forfeiture rate	12.0%	14.0%	n/a

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*Expected Price Volatility* - This is a measure of the amount by which a price has fluctuated or is expected to fluctuate. During 2007, the Company based its determination of expected volatility on its historical stock price volatility. Prior to 2007, the Company used an average expected price volatility of other publicly traded biopharmaceutical companies because the Company believed that it was the best indicator of future volatility, since the Company had less than two years of its own historical stock price volatility. This change in estimate did not have a material effect on the Company's results from operations for the year ended December 31, 2007. An increase in the expected price volatility will increase compensation expense.

*Risk-Free Interest Rate* - This is the U.S. Treasury rate for the week of the grant having a term approximating the expected life of the option. An increase in the risk-free interest rate will increase compensation expense.

*Expected Life* - This is the period of time over which the options granted are expected to remain outstanding and is determined by calculating the average of the vesting term and the contractual term of the options, as allowed by SAB 107. The Company has utilized this method due to the lack of historical option exercise information related to the Company's stock option plans. Options granted have a maximum term of ten years. An increase in the expected life will increase compensation expense.

*Dividend Yield* - The Company has not made any dividend payments nor does it have plans to pay dividends in the foreseeable future. An increase in the dividend yield will decrease compensation expense.

*Forfeiture Rate* - This is the estimated percentage of options granted that are expected to be forfeited or canceled before becoming fully vested. The forfeiture rate is estimated at the time of valuation and reduces expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

The following is a summary of stock option transactions for all of the Company's stock option plans for the three year period ended December 31, 2007:

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at January 1, 2005 .....	1,143,207	\$ 7.66
Options granted .....	236,000	10.71
Options forfeited .....	(73,206)	6.83
Options exercised .....	(4,251)	8.87
Options outstanding at December 31, 2005 .....	1,301,750	8.27
Options granted .....	225,834	8.50
Options forfeited .....	(40,500)	9.42
Options exercised .....	(28,795)	5.32
Options outstanding at December 31, 2006 .....	1,458,289	8.33
Options granted .....	566,417	18.23
Options forfeited .....	(36,500)	12.70
Options exercised .....	(108,554)	7.61
Options outstanding at December 31, 2007 .....	<u>1,879,652</u>	11.27

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The following table summarizes information about stock options outstanding at December 31, 2007:

Options Outstanding			Options Exercisable		
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$2.24	17,775	2.89	\$ 2.24	17,775	\$ 2.24
\$2.25 - \$7.85	761,044	5.54	6.64	492,110	6.49
\$7.86 - \$20.45	1,100,833	8.14	14.61	169,549	11.75
	<u>1,879,652</u>	7.04	11.27	<u>679,434</u>	7.69

At December 31, 2007, the aggregate intrinsic value of all outstanding options was \$7,967 with a weighted average remaining contractual term of 7.04 years, of which 679,434 of the outstanding options are currently exercisable with an aggregate intrinsic value of \$4,530, a weighted average exercise price of \$7.69 and a weighted average remaining contractual term of 5.25 years. There were 108,554 options exercised during the year ended December 31, 2007. The total intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was \$1,191, \$204, and \$11, respectively. At December 31, 2007, the total compensation cost related to non-vested awards not yet recognized was \$5,047 with a weighted average expense recognition period of 2.08 years. Options available for future issuance under the Company's stock option plans were 1,774,536 at December 31, 2007. On January 1, 2008, options available for future issuance increased to 2,830,203 in accordance with the provisions of the Company's stock option plans.

#### 4. Property and Equipment, Net

Property and equipment consist of the following:

	December 31,	
	2007	2006
Laboratory and office equipment .....	\$ 3,080	\$ 2,633
Leasehold improvements.....	669	669
Furniture and fixtures.....	328	312
Computer equipment and software.....	1,581	1,209
In process equipment and software .....	491	136
	<u>6,149</u>	<u>4,959</u>
Less: accumulated depreciation.....	(3,841)	(3,023)
	<u>\$ 2,308</u>	<u>\$ 1,936</u>

Depreciation and amortization expense for the years ended December 31, 2007, 2006 and 2005 was \$841, \$842 and \$736, respectively. Of these amounts, \$388, \$403 and \$468, respectively, were included in research and development expenses in the statements of operations.

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**5. Accrued Expenses**

Accrued expenses consist of the following:

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Research and development .....	\$ 3,314	\$ 627
Clinical trial .....	1,502	1,117
Other .....	1,475	924
Professional fees .....	493	481
	<u>\$ 6,784</u>	<u>\$ 3,149</u>

**6. Intangible Assets**

Intangible assets consist of the following:

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
License fees .....	\$ 5,339	\$ 4,826
Less: accumulated amortization .....	(909)	(600)
	<u>\$ 4,430</u>	<u>\$ 4,226</u>

In accordance with the terms of the Amended and Restated License and Supply Agreement that the Company entered into with Orion in December 2004 ("Orion License and Supply Agreement"), the Company was required to pay a license fee of \$4,826. This license fee is being amortized on a straight-line basis over the term of the Orion License and Supply Agreement which the Company estimates to be 16 years. In accordance with the terms of the Consolidated, Amended, and Restated License Agreement ("SARM License") and the Amended and Restated License Agreement ("SERM License") that the Company entered into with the University of Tennessee Research Foundation ("UTRF") in July 2007 and September 2007, respectively, the Company paid a one-time up-front fee of \$290 per license. The license fees under the SARM License and SERM License are being amortized on a straight-line basis over the respective terms of the agreements, which the Company estimates to be approximately 14 years and 11.5 years, respectively. Amortization expense for the years ended December 31, 2007, 2006 and 2005 was \$309, \$298 and \$302, respectively. See Note 8 for additional information on intangible assets. See also Note 2 for additional information on the reclassification of the prior period computer software balance from intangible assets to property and equipment.

Estimated future amortization expense for purchased intangible assets at December 31, 2007 is as follows:

<b>Years Ending December 31,</b>	
2008	\$ 332
2009	332
2010	332
2011	332
2012	332
Thereafter	2,770
Total	<u>\$ 4,430</u>

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**7. Common and Preferred Stock**

The Company's certificate of incorporation authorizes the Company to issue 60,000,000 shares of common stock with \$0.001 par value per share and 5,000,000 shares of preferred stock, par value \$0.001.

On October 17, 2005, the Company completed an underwritten public offering of 6,325,000 shares of common stock including the exercise of the over-allotment option by the underwriters, at a price to the public of \$7.80 per share. Net cash proceeds from this offering were \$45,663 after deducting underwriting discounts and other offering expenses.

On December 18, 2006, the Company completed a public offering of 3,799,600 shares of common stock at a price to the public of \$16.00 per share. Net cash proceeds from this offering were \$57,426 after deducting placement agent fees and other offering expenses.

On December 18, 2007, the Company completed a private placement of 1,285,347 shares of common stock to Merck at a per share price of \$23.34 (see Note 8).

**8. Collaboration and License Agreements**

***Merck & Co., Inc.***

On November 5, 2007, GTx and Merck entered into a global Exclusive License and Collaboration Agreement (the "Merck Collaboration Agreement") governing the Company's and Merck's joint research, development and commercialization of SARM compounds and related SARM products, including SARMS currently being developed by the Company and Merck and those yet to be discovered, for all potential indications of interest. The Collaboration Agreement became effective on December 18, 2007.

Under the Merck Collaboration Agreement, the Company has granted Merck an exclusive worldwide license under its SARM-related patents and know-how. The Company will conduct preclinical research of SARM compounds and products, and Merck will be primarily responsible for conducting and funding development and commercialization of products developed under the Merck Collaboration Agreement. Merck has agreed to pay the Company an upfront licensing fee of \$40,000, which was received in January 2008. In addition, Merck has agreed to pay the Company \$15,000 in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the Merck Collaboration Agreement. The Company is also eligible to receive under the Merck Collaboration Agreement up to \$422,000 in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine™, as defined in the Merck Collaboration Agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the Merck Collaboration Agreement. Merck has also agreed to pay the Company tiered royalties on net sales of products that may be developed under the Merck Collaboration Agreement. The Company is responsible for any payments owed to UTRF resulting from the Merck Collaboration Agreement.

Unless terminated earlier, the Merck Collaboration Agreement will remain in effect in each country of sale at least until the expiration of all valid claims of the licensed patents in such country. However, Merck may terminate the Merck Collaboration Agreement at its election at any time after a specified period of time following the effectiveness of the Merck Collaboration Agreement, and either party may terminate the Merck Collaboration Agreement at any time for the other party's uncured material breach or bankruptcy. Under certain conditions, Merck will continue to owe royalties on certain products after it terminates the Merck Collaboration Agreement without cause.

The Company and Merck also entered into a Stock Purchase Agreement on November 5, 2007 pursuant to which the Company agreed to sell and Merck agreed to purchase at the closing on December 18, 2007, 1,285,347

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newly-issued shares of the Company's common stock for an aggregate purchase price of approximately \$30,000, or \$23.34 per share. The per share price of \$23.34 represents 140% of the average of the last reported sales prices of the Company's common stock for the 30 consecutive trading days ended November 2, 2007.

The Company deferred the recognition of the upfront licensing fee of \$40,000 and the \$10,800 in equity premium received that represents the difference between the purchase price and the closing price of the Company's common stock on the date the stock was purchased by Merck. These payments are being recognized as revenue over the period of the Company's performance obligation, which the Company estimates to be ten years. The Company recognized as collaboration revenue \$198 for the year ended December 31, 2007 from the amortization of the Merck deferred revenue. Cost reimbursements for research and development activities will begin to be recognized as collaboration revenue when the amounts are determinable and collection of the related receivable is reasonably assured.

***Ipsen Collaboration and License Agreement***

In September 2006, the Company entered into a collaboration and license agreement with Ipsen pursuant to which the Company granted Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE<sup>®</sup> and other products containing toremifene in all indications which the Company has licensed from Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. In accordance with the terms of the license agreement, Ipsen has agreed to pay the Company €23,000 as a license fee and expense reimbursement, of which €1,500 is to be paid in equal installments over a three year period from the date of the agreement. In October 2006, the Company received €21,500 (approximately \$27,100) from Ipsen as the initial payment for the license fee and expense reimbursement. In September 2007, the Company received €500 (approximately \$688) from Ipsen as the first annual installment payment. Pursuant to the agreement, GTx is also entitled to receive from Ipsen up to an aggregate of €39,000 in milestone payments depending on the successful development and launch of ACAPODENE<sup>®</sup> in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. Ipsen has agreed to be responsible for and to pay all clinical development, regulatory and launch activities to commercialize ACAPODENE<sup>®</sup> in the European Territory for both the high grade PIN indication and ADT indication. Ipsen has agreed to pay the Company a royalty equal to a graduating percentage of aggregate net sales of products containing toremifene (including ACAPODENE<sup>®</sup>) which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. GTx will remain responsible for paying upstream royalties on ACAPODENE<sup>®</sup> to both Orion and UTRF for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

The Company recorded deferred revenue of \$29,259 related to the Ipsen upfront license fee and expense reimbursement which is expected to be amortized into revenue on a straight-line basis over the estimated five year development period for ACAPODENE<sup>®</sup> in the European Territory. The Company recognized as collaboration revenue \$5,852 and \$1,853 for the years ended December 31, 2007 and 2006, respectively, from the amortization of the Ipsen deferred revenue.

***University of Tennessee Research Foundation License Agreements***

On July 24, 2007, the Company and UTRF entered into the SARM License to consolidate and replace the Company's two previously existing SARM license agreements with UTRF and to modify and expand certain rights and obligations of each of the parties under both license agreements. Pursuant to the SARM License, the Company was granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University.

On September 24, 2007, the Company and UTRF entered into the SERM License to replace the Company's previously existing exclusive worldwide license agreement for ACAPODENE<sup>®</sup>. Pursuant to the SERM License, the



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Company was granted exclusive worldwide rights to UTRF's method of use patents relating to SERMs, including ACAPODENE<sup>®</sup> for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee.

Under both the SARM License and the SERM License, the Company agreed to pay to UTRF a one-time, upfront fee of \$290 per license. The Company is also obligated to pay UTRF annual license maintenance fees and royalties on sublicense revenues and net sales of products.

***Orion Corporation License and Supply Agreement***

On December 29, 2004, the Company entered into the Orion License and Supply Agreement granting the Company exclusive rights to Orion's compound, toremifene, for all products for human uses, including the Company's product candidate, ACAPODENE<sup>®</sup>, excluding, however, products for breast cancer sold outside of the United States. The Orion License and Supply Agreement, which has an effective date of January 1, 2005, replaces an earlier agreement entered into with Orion in 2000, and subsequently amended in 2001 and 2003 ("Original Orion License"). Under the Orion License and Supply Agreement, the Company was required to pay a license fee of \$4,826. The term of the Orion License and Supply Agreement will survive for the term of the Company's patents, including the Company's patents to treat complications arising from ADT and the patents it licenses from UTRF for the treatment and/or prevention of PIN and prostate cancer. The term of the Company's method of use patents extend from 2019 to 2023.

Under the Original Orion License, the Company paid Orion \$400, which it is allowed to offset along with clinical trial expenses against licensing fees and milestone payments it will pay to Orion if the Company sublicenses rights to its patents to third parties. The Orion License and Supply Agreement retains these provisions and obligates the Company to make future royalty payments of varying amounts for toremifene based products for breast cancer in the United States and to treat or prevent PIN or prostate cancer or to treat complications arising from ADT.

The Company has agreed to achieve specified minimum sales requirements of ACAPODENE<sup>®</sup> in the United States after commercialization of the product or it must pay Orion royalties based on the amount of the shortfall. In addition, the Company is required to pay up to \$1,000 if the Company is acquired before receiving marketing approval for the use of ACAPODENE<sup>®</sup> for the prevention or treatment of PIN or prostate cancer or to treat complications arising from ADT. Orion may terminate the Orion License and Supply Agreement if marketing approval for ACAPODENE<sup>®</sup> is not granted in the United States by December 31, 2009.

***Ortho Biotech Collaboration and License Agreement***

In March 2004, the Company entered into a joint collaboration and license agreement with Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson ("Ortho Biotech"), for andarine and specified backup SARM compounds. Under the terms of the agreement, the Company received in April 2004 an upfront licensing fee and expense reimbursement totaling \$6,687. The upfront licensing fee and expense reimbursement were deferred and amortized into revenue on a straight-line basis over the estimated five year andarine development period. In December 2006, the Company reacquired full rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech, and the joint collaboration and license agreement was terminated by mutual agreement of the parties. In connection with the termination of the Ortho Biotech agreement, the Company recognized the associated \$3,100 balance of deferred revenue as additional collaboration revenue. The Company recognized revenue of \$4,295 and \$1,337 for the years ended December 31, 2006 and 2005, respectively, from the amortization of the upfront license fee and expense reimbursement.

**9. Income Taxes**

We have incurred net losses since inception and, consequently, have not recorded any U.S. federal and state income taxes. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

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The principal components of the Company's net deferred income tax assets consist of the following:

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Deferred income tax assets:		
Net federal and state operating loss carryforwards.....	\$ 57,252	\$ 38,921
Research and development credits .....	6,200	4,614
Cash basis method .....	-	641
Deferred stock compensation .....	2,010	1,185
Deferred revenue .....	7,511	10,319
Total deferred tax assets .....	<u>72,973</u>	<u>55,680</u>
Deferred income tax liabilities:		
Depreciation and amortization .....	66	84
Other .....	284	-
Total deferred tax liabilities.....	<u>350</u>	<u>84</u>
Net deferred income tax assets .....	72,623	55,596
Valuation allowance .....	(72,623)	(55,596)
	<u>\$ -</u>	<u>\$ -</u>

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$17,027, \$14,690 and \$15,047 in 2007, 2006 and 2005, respectively.

At December 31, 2007, the Company had net federal operating loss carryforwards of approximately \$150,000, which expire from 2018 to 2027 if not utilized. The Company had state operating loss carryforwards of approximately \$112,718, which expire from 2013 to 2022 if not utilized. The Company also had research and development credits of \$6,200, which expire from 2018 to 2027 if not utilized.

Utilization of the net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986, as amended and similar state provisions. The annual limitations may result in the expiration of net operating loss carryforwards before utilization.

#### **10. Directors' Deferred Compensation Plan**

Since June 30, 2004, non-employee directors have had the opportunity to defer all or a portion of their fees under the Company's Directors' Deferred Compensation Plan until termination of their status as directors. Deferrals can be made into a cash account, a stock unit account, or a combination of both. Stock unit accounts will be paid out in the form of Company common stock, except that any fractional shares will be paid out in cash valued at the then current market price of the Company's common stock. Cash accounts and stock unit accounts under the Directors' Deferred Compensation Plan are credited with interest or the value of any cash and stock dividends, as applicable. Non-employee directors are fully vested in any amounts that they elect to defer under the Directors' Deferred Compensation Plan.

For the years ended December 31, 2007, 2006 and 2005, the Company incurred board of director fee expense of \$207, \$163 and \$192, respectively, of which \$183, \$140 and \$180 was deferred and will be paid in common stock. At December 31, 2007, 43,367 stock units had been credited to individual director stock unit accounts.

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**NOTES TO FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

**11. 401(k) Plan**

The Company sponsors a 401(k) retirement savings plan that is available to all eligible employees. The plan is intended to qualify under Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan provides that each participant may contribute up to a statutory limit of their pre-tax compensation which was \$15.5 for employees under age 50 and \$20 for employees 50 and older in calendar year 2007. Employee contributions are held in the employees' name and invested by the plan's trustee. The plan also permits the Company to make matching contributions, subject to established limits. The Company elected to match a portion of employee's contributions to the plan in the amount of \$210 and \$89 in 2007 and 2006, respectively.

**12. Commitments and Contingencies**

***Operating Lease Commitments***

The Company leases laboratory facilities and office space pursuant to a lease, which is accounted for as an operating lease. The lease expires December 31, 2008, with an option to extend for up to two additional years and is terminable by either party upon 90 days' notice. In addition, in December 2007, the Company entered into a sublease for additional office space. This new office space sublease will be accounted for as an operating lease and has a term from January 1, 2008 through April 15, 2015. The Company has an option to cancel this sublease beginning December 31, 2010. Rent expense was approximately \$765, \$712 and \$599 for the years ended December 31, 2007, 2006 and 2005, respectively.

As of December 31, 2007, minimum payments under operating lease arrangements were as follows:

2008	\$ 323
2009	446
2010	611
Total	<u>\$ 1,380</u>

***Purchase Commitments***

The Company had outstanding contractual purchase obligations of \$280 and \$19 at December 31, 2007 and 2006, respectively. These outstanding contractual purchase obligations are not recorded in the accompanying financial statements as the amounts represent future obligations, not liabilities, at December 31, 2007 and 2006 respectively.

**GTx, Inc.**  
**NOTES TO FINANCIAL STATEMENTS**  
(in thousands, except share and per share data)

**13. Quarterly Financial Data (Unaudited)**

The following is a summary of the quarterly results of operations for the years ended December 31, 2007 and 2006.

	Fiscal 2007 Quarters Ended			
	March 31	June 30	September 30	December 31
Revenues:				
Product sales, net.....	\$ 192	\$ 360	\$ 268	\$ 256
Collaboration revenue.....	1,463	1,463	1,463	1,661
Total revenues	1,655	1,823	1,731	1,917
Costs and expenses:				
Cost of product sales.....	109	206	148	158
Research and development expenses.....	8,007	8,575	9,881	12,045
General and administrative expenses.....	3,117	3,609	3,182	3,593
Total costs and expenses.....	11,233	12,390	13,211	15,796
Loss from operations.....	(9,578)	(10,567)	(11,480)	(13,879)
Interest income.....	1,454	1,364	1,238	1,089
Net loss.....	\$ (8,124)	\$ (9,203)	\$ (10,242)	\$ (12,790)
Net loss per share:				
Basic.....	\$ (0.23)	\$ (0.26)	\$ (0.29)	\$ (0.36)
Diluted.....	\$ (0.23)	\$ (0.26)	\$ (0.29)	\$ (0.36)

	Fiscal 2006 Quarters Ended			
	March 31	June 30	September 30	December 31
Revenues:				
Product sales, net.....	\$ 876	\$ 288	\$ 348	\$ (155)(a)
Collaboration revenue.....	334	335	724	4,755 (b)
Total revenues	1,210	623	1,072	4,600
Costs and expenses:				
Cost of product sales.....	467	170	118	18
Research and development expenses.....	8,441	8,444	9,614	7,398
General and administrative expenses.....	2,950	2,692	2,867	2,843
Total costs and expenses.....	11,858	11,306	12,599	10,259
Loss from operations.....	(10,648)	(10,683)	(11,527)	(5,659)
Interest income.....	724	699	638	946
Net loss.....	\$ (9,924)	\$ (9,984)	\$ (10,889)	\$ (4,713)
Net loss per share:				
Basic.....	\$ (0.32)	\$ (0.32)	\$ (0.35)	\$ (0.15)
Diluted.....	\$ (0.32)	\$ (0.32)	\$ (0.35)	\$ (0.15)

- (a) Decrease in net product sales reflects the increase during the quarter to the Company's reserve for FARESTON<sup>®</sup> product returns. See Note 2, Revenue Recognition.
- (b) Increase reflects amortization of Ipsen deferred revenue for the entire quarter and recognition of the remaining balance of Ortho Biotech deferred revenue in connection with the termination of the Ortho Biotech agreement. See Note 8, Collaboration and License Agreements.

**BOARD OF DIRECTORS**

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SV Life Sciences Advisers, LLP,  
former International Marketing  
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**MANAGEMENT**

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**END**